"ICE-MINUS": A CASE STUDY OF EPA'S REVIEW OF GENETICALLY ENGINEERED MICROBIAL PESTICIDES

HEARING

BEFORE THE

SUBCOMMITTEE ON
INVESTIGATIONS AND OVERSIGHT

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

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"ICE-MINUS": A CASE STUDY OF EPA'S REVIEW OF GENETICALLY ENGINEERED MICROBIAL PESTICIDES

TUESDAY, MARCH 4, 1986

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:06 p.m., in room 2325, Rayburn House Office Building, Hon. Harold Volkmer (chairman of the subcommittee) presiding.

Mr. VOLKMER. The Subcommittee on Investigations and Oversight will come to order.

This hearing is being held to examine the facts of what appears to be the first deliberate release into the environment of genetically engineered organisms. In February 1985, Advanced Genetic Sciences, Inc., reportedly injected fruit trees located on the roof of their office building in Oakland, CA, with bacteria that had been genetically engineered to prevent the formation of frost on plants. Neither the Environmental Protection Agency nor any other governmental agency was aware of these tests.

At the time in early 1985, when Advanced Genetic Sciences was conducting these rooftop tests, it was also applying to EPA for approval to conduct field tests of the bacteria in Monterey, CA. In November 1985, EPA approved the field tests.

This subcommittee convened a hearing in December 1985 to discuss the issue of deliberate release of genetically engineered organisms into the environment. At the hearing, EPA assured the subcommittee that it had extensively reviewed the data from Advanced Genetic Sciences before approving the field tests.

Recently, we all learned that these rooftop tests were conducted before EPA had approved the field tests without EPA's knowledge. In addition, we learned that EPA has never visited the site for the field tests. If EPA had visited the site, EPA would have discovered, as the citizens of Monterey County know, that the test site is located in the middle of a residential neighborhood.

This incident underscores the need for diligent governmental review of biotechnology. Three Mile Island and Love Canal show how difficult it is to put the technological genie back into the bottle after it has escaped. We cannot have a similar instance in the area of biotechnology. We must never find ourselves in the position of needing a Superfund to clean up the products of biotechnology.

I believe that much of the public is supportive of the biotechnology industry and the promise that technology holds for combating hunger and disease. But development of the industry must proceed in a manner that protects our health and the environment or biotechnology will lose the most important element in its success, the public's confidence and support. These unauthorized tests and the omissions in EPA's review of the proposed field test site have eroded that confidence.

Today, we have invited representatives from Advanced Genetic Sciences, from EPA, and from EPA's Science Advisory Board to discuss how these events could have occurred and what actions we must take to prevent such future occurrences. We have also invited the chairman of the Monterey County Board of Supervisors and a representative of local concerned citizens to share their perspectives along with their Representative here in Congress.

I would like to now recognize the gentleman from California for any opening statement that he may wish to make.

Mr. PACKARD. Thank you, Mr. Chairman.

The Investigations and Oversight Subcommittee has been keenly interested in genetic engineering since the pioneer days of recombinant DNA research. The subcommittee has been very encouraged by the competitive and economic benefits promised by biotechnology research. Yet, the subcommittee is very much aware of the need to ensure protection of human health and the environment.

The administration and the executive branch have done a commendable job in trying to reach a balance between competitive advantages and safety by moving quickly to formulate a Federal regulatory policy. On October 17, 1984, the Environmental Protection Agency issued its interim policy on small-scale field testing of microbial pesticides. Shortly thereafter, on December 31, 1984, the Office of Science and Technology Policy issued its proposal for a coordinated framework for regulation of biotechnology.

The final regulatory framework is expected to be published in the next several weeks. The policy reflects an understanding of the need to strike a balance between encouraging the developments of this promising industry and protecting the health and well-being of our citizens and the environment.

Government's swift response to the regulatory needs of this new technology has been greatly aided by the biotechnology industry itself. The industry has gone out of its way to cooperate with the Federal Government to ensure that human health and the environment are protected.

The industry realizes that only by thoroughly evaluating the risks associated with the deliberate release of genetically engineered organisms into the environment can the industry hope to remain competitive and profit from their investments. The biotechnology industry agrees that a balance must be reached between corporate profits and safety.

The action taken by Advanced Genetic Sciences was a breach of the public's trust and flies in the face of the progress that we have made and that their own industry has achieved. It is an unfortunate incident that runs the risk of adversely impacting upon other biotechnology companies that have done a commendable job in addressing the public's concern about this technology.

I am confident that the action taken by AGS is and will be the exception rather than the rule. I commend you, Mr. Chairman, for calling this hearing and believe today's testimony will help us understand why this incident occurred and how the Federal Government can fine tune the present regulatory system.

I want to emphasize that I do not believe that the response to this incident should be imposing additional stringent regulations. Punishing an entire industry and our Nation's economic future for one careless action of one company would not be a fair or responsible action on our part.

Mr. Chairman, we should be aware that any actions taken as a result of this hearing could have long-term effects, and we should be sensitive to the excellent research being done in the genetic field.

Thank you very much.

Mr. VOLKMER. I thank you.

There may be some still photos taken, so at this time, without objection, we will permit the taking of photographs and video taping of the proceedings.

Mr. PACKARD. I have no objection.

Mr. VOLKMER. All right.

Our first witness is Dr. John R. Bedbrook, vice president and director of research of Advanced Genetic Sciences. I ask Dr. Bedbrook to please come to the witness table and, before proceeding, I would appreciate it if you would please raise your right hand and take the following oath: Do you swear to tell the truth, the whole truth, and nothing but the truth, so help you God?

Dr. BEDBROOK. I do.

Mr. VOLKMER. You may be seated. Your statement, which you have been so kind as to furnish us, will be made a part of the record at this point in the record. You may either summarize or review the statement in full, however you so desire. You may begin.

Dr. BEDBROOK. Mr. Chairman, I would like to summarize the statement. My oral comments should take approximately 10 minutes.

Mr. VOLKMER. That is quite all right.

STATEMENT OF DR. JOHN R. BEDBROOK, VICE PRESIDENT AND DIRECTOR OF RESEARCH, ADVANCED GENETIC SCIENCES, OAKLAND, CA

Dr. BEDBROOK. Good afternoon. I am John Bedbrook, vice president and director of research for Advanced Genetic Sciences. AGS is located in Oakland, CA, and is housed in a facility leased from the University of California. I have served as director of research for AGS since 1982. Prior to that time, I was a senior research scientist at the division of plant industry at the CSIRO in Canberra, Australia. Prior to that, I did postdoctoral research at the Plant Breeding Institute in Cambridge, England, and at the Harvard Biological Laboratories and at Harvard Medical School. I received my Ph.D. degree in 1974 at the University of Auckland in New Zealand, and my present responsibilities at AGS include designing, funding responsibilities, and managing of the research program.

AGS is a small, public company founded in 1979 for the purpose of developing products for the agricultural and food processing markets through the application of techniques developed in modern biology. I have provided the subcommittee with copies of our 1984 annual report and would refer you to those documents for corporate and financial information concerning the company.

Over the past 3 years, one project at AGS has been the development of genetically engineered organisms designed to protect certain plants from frost damage. We call these organisms Frostban. It is a limited field test of these AGS products on a small approximately one-fifth-acre plot of strawberries that is the subject of the experimental use permit recently issued by EPA to AGS and the subject of several recent newspaper articles and the focus of this subcommittee hearing.

In my oral remarks before the subcommittee this afternoon, I would like to describe the Frostban organisms, the nature of the proposed field test, AGS efforts to obtain National Institutes of Health and Environmental Protection Agency approval of the field test, and I would also like to mention recent developments concerning certain tests performed outdoors at the AGS facilities last week.

As I mentioned earlier, one project in our extensive research and development program has produced two experimental microorganisms which have commercial potential for limiting losses due to frost and freezing. Frost damage to plant tissues occurs at temperatures slightly below freezing because certain bacteria which exist in nature on the surface of plant leaves and blossoms act as catalysts to ice crystal formation. In the absence of these bacteria, ice crystals do not form on the plant tissues until the temperature drops significantly below freezing. The Frostban microorganisms act by preempting growth of the natural bacteria that catalyze ice crystal formation thereby protecting the plants from frost damage.

We have produced Frostban by a simple, genetic modification of two common, naturally occurring species of bacteria. This modification involves removing portions of the genes that make those strains ice-nucleation active. This is the only change we have made. No foreign, genetic material has been introduced. No other genes have been altered in any other way.

The altered bacteria resulting from this small and precise modification are called INA-minus and are identical to the parent strains except that they lack the ice-nucleating ability.

If the principle of Frostban works, other similar organisms can be developed to protect other food crops from frost damage and to control other plant pests. Effective frost-damage prevention of this type has substantial potential value, as over $1 billion of crops are lost to frost and freezing each year. We believe this and related products could be of great value in years to come in expanding the world food supply and preventing significant economic losses to agriculture.

AGS has come to the point in the development of this product where it must test the product under natural field conditions. The field test that AGS has proposed is a well-controlled application of Frostban organisms on strawberry plants in about an 81- by 81-foot

area. The purpose is to test the ability of Frostban to compete with the organisms in the natural environment.

Two Federal agencies have played principle roles in the review of the approval of the AGS application to conduct this field test. On March 22, 1984, we notified the NIH Recombinant DNA Advisory Committee, the RAC, about our field test proposal. As a private company, we were not required to seek NIH approval, but we voluntarily notified the RAC because we were aware of public concern about deliberate release experiments, and we did not wish to go forward without the support of the scientific community and public confidence that RAC approval would provide.

The RAC voted unanimously to recommend approval by NIH provided that certain additional monitoring be required for the field test and certain additional data be supplied by AGS prior to NIH approval. AGS was notified of this action by letter, dated October 18, 1984, and in response, AGS submitted additional data to NIH by letter, dated November 15, 1984.

In the meantime, the EPA was considering how it should regulate products of biotechnology under the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA] and the Toxic Substances Control Act [TSCA]. EPA issued its interim policy on small-scale field testing of microbial pesticides under FIFRA on October 17, 1984.

The EPA interim policy requires notification of the agency prior to field testing certain microbial pesticides. If the Agency determines the field test should be subject to more in depth review, it requires the proponents to obtain an experimental-use permit before conducting the test.

EPA considers our INA-minus bacteria to be pesticides because they mitigate frost by competing with the pest INA-plus bacteria. We were therefore required, under the interim policy, to notify EPA of our proposal to test this organism in the field. Given the need to obtain approval of the field test by EPA, we later withdrew our voluntary effort to obtain NIH approval.

On November 14, 1985, the EPA approved issuance of the experimental-use permit.

Last week, several newspapers carried stories about the tests done by AGS to confirm that Frostban bacteria are not pathogenic to various types of plants. These articles carried a number of unsubstantiated and unattributed allegations about the data AGS supplied to EPA as well as allegations that one of the tests performed by AGS violated the EPA interim policy on experimental field tests. Because these articles have caused public concern about the quality of data AGS offered in support of its application, we have addressed each of these allegations, and let me make this in my oral statement.

First, let me address the question of whether tests done by AGS complied with EPA interim policy. In response to EPA's request for additional data regarding pathogenicity, AGS planned a comprehensive program of tests designed to furnish EPA with the data it requested. All of these tests were conducted in the AGS greenhouse located on the roof of the AGS facilities in Oakland with the exception of one series of tests which took place outdoors on the roof. The rooftop facilities are shown on page 5 of our annual report for your information. A large aerial photograph has been provided to

your staff which shows the location of the AGS facilities in relation to the surrounding area.

The purpose of the particular test was to confirm that AGS-altered bacteria are not pathogenic in several types of fruit trees. In general, these tests consisted of injecting four kinds of material at different sites on small branches of several types of fruit trees. The trees were observed for up to 7 months for the development of pathogenic reactions.

Pathogenic reactions were observed only at those sites injected with known pathogens. These reactions were evident within 2 weeks.

EPA apparently believes that the tests AGS performed outdoors on the roof do not comply with the EPA interim policy on small-scale field tests of microbial pesticides. While with hindsight we can certainly understand EPA's interpretation of its interim policy, I would like to explain how AGS interpreted the EPA requirements at the time that the experiments were conducted.

The choice of the outdoor rooftop space for the tree tests was a pragmatic one based on the physical space requirements and the duration of that experiment. All these trees could not be physically contained within the greenhouse if the other pathogenicity and related experiments were to be conducted at the same time.

The EPA was not notified of plans to use the outdoor space because the scientists involved did not interpret the use of the outdoor roof area for tree branch injections as an environmental release subject to the EPA interim policy. The proposed spraying of Frostban in an agricultural setting is the kind of release they believed to be subject to notification requirements. They believe the inoculation methods to be used on the rooftop tests would minimize any potential for release, and they were confident that the test organisms were not pathogens and, therefore, would not multiply in the fruit trees.

Thus, they were confident that the tests involving the injection of bacteria into branches of trees located on the roof would not constitute any greater risk of an environmental release than a greenhouse experiment because the injected bacteria would be contained within the plant tissue and the tissue would be sterilized and properly disposed of at the conclusion of the experiment.

In short, the experiment was done outdoors on the rooftop without prior notice to EPA because the researchers felt that the experiment did not constitute a field test and that the methodology and physical environment provided containment and did not involve a direct release of altered bacteria to the environment.

While AGS believes its researchers acted in good faith in their interpretation of EPA requirements, we do not wish to press for this view of the meaning of field test or containment as the proper interpretation of the EPA interim policy. We are quite prepared to accept EPA's judgment on the appropriate interpretation of their regulations and to conduct our future work accordingly.

The controversy surrounding the outdoor test did not arise as a consequence of any inadequacy of the EPA interim policy nor as a consequence of any conscious disregard of that policy by AGS scientists. The tree pathogenicity tests took place as a result of a responsible decision made by qualified and cautious people who interpret-

ed the procedural requirements of the EPA policy with insufficient sensitivity of the importance of having EPA, acting on behalf of the public, share in making even that most cautious decision.

The issue whether performance of the outdoor tests complied with the notification requirements of the EPA interim policy does not affect the quality of the data the tests supplied to the EPA. The results of our pathogenicity tests are unequivocal, and we stand behind them.

In closing, I would like to turn my attention to the concerns expressed by the local citizens of Monterey County, the county in which the field test is to be carried out. I understand that Mr. Sam Karas, chairman of the Monterey County Board of Supervisors, will be testifying later in the hearing about local community concerns, so I will be brief.

AGS has learned a great deal over the past several weeks about how the public perceives our work and the prospect of a release of genetically engineered organisms. While most recognize the enormous potential benefits of biotechnology, there is a great lack of knowledge about microorganisms and a deep concern about the potential risks involved.

This is understandable, and we scientists must work harder to help the public learn more about what we do so that the public can better discern, along with us, the difference between those activities which may present significant risks and those which present only negligible risks, if any. Public education has not kept pace with our science, and the scientific community and industries that use biotechnology must attend to this if we are to continue to advance toward useful and beneficial applications of the science.

In addition, the public should be given adequate opportunity to participate in decision making on biotechnology issues. AGS is hopeful that EPA and the other Federal agencies having jurisdiction over biotechnology products will review their procedures to assure that any local communities affected by proposed actions are given early notice and a full opportunity to comment.

We also plan to do a better job ourselves of establishing communications with the communities in which we do our field test work.

In conclusion, I want to thank you for the opportunity to speak before the subcommittee. There has been a great deal of misinformation in newspapers about our field test proposal, and this hearing has provided us an excellent opportunity to correct any misunderstandings. AGS appreciates the opportunity to review these issues with you, and we look forward to working with Federal, State, and local authorities to assure you that our work meets all the appropriate standards for biotechnology research.

Thank you.

[The prepared statement of Dr. Bedbrook follows:]

STATEMENT OF JOHN R. BEDBROOK
VICE PRESIDENT, DIRECTOR OF RESEARCH
ADVANCED GENETIC SCIENCES
BEFORE THE
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES
MARCH 4, 1986

Good afternoon. I am John R. Bedbrook, Vice President and Director of Research for Advanced Genetic Sciences (AGS). AGS is located in Oakland, California and is housed in a facility leased from the University of California. I have served as Director of Research for AGS since 1982. Prior to that time, I was a Senior Research Scientist at the Division of Plant Industry, CSIRO, Canberra, Australia. I did postdoctoral research under three different fellowships at the Plant Breeding Institute in Cambridge, England, at Harvard Biological Laboratories and at Harvard Medical School. I received my Ph.D degree in 1974 from the University of Auckland in New Zealand. My present responsibilities at AGS include designing, funding, and managing the research program.

I. INTRODUCTION

AGS is a small public company founded in 1979 for the purpose of developing products for the agricultural and food processing markets through the application of techniques developed in modern biology. I have provided the Subcommittee

with copies of our 1984 annual report and would refer you to that document for corporate and financial information about the company. At present, AGS employs 99 people, 76 of whom are involved in research, including 29 Ph.D. scientists. Our scientific staff includes scientists with extensive educational backgrounds and experience in areas related to microbiology, plant pathology, cell biology, biochemistry, and genetics, as well as genetic engineering.

I understand that this particular Subcommittee has spent many hours looking into the implications of biotechnology, and genetic engineering in particular, and is quite familiar with the great promise that biotechnology holds for significant advances in medicine, industry and agriculture. Over the past three years, one project at AGS has been the development of genetically engineered organisms designed to protect certain plants from frost damage. We call these organisms "Frostban." It is a limited field test of this AGS product on a small approximately one-fifth of an acre plot of strawberries that is the subject of the experimental use permit recently issued by EPA to AGS, the subject of several recent newspaper articles and the focus of this Subcommittee hearing.

In my remarks before the Subcommittee this afternoon, I would like to describe the Frostban organisms, the nature of the proposed field test, AGS' efforts to obtain National

Institutes of Health (NIH) and Environmental Protection Agency (EPA) approval of the field test and recent developments concerning certain tests performed outdoors at the AGS facilities last year.

II. EXPERIMENTAL USE PERMIT

A. Nature of the Frostban Organism

As I mentioned earlier, one project in our extensive research and development program has produced two experimental microorganisms which have commercial potential for limiting crop losses due to frost and freezing. Frost damage to plant tissues occurs at temperatures slightly below freezing because certain bacteria, which exist in nature on the surface of plant leaves and blossoms, act as catalysts to ice crystal formation. In the absence of these bacteria, ice crystals do not form on the plant tissues until the temperature drops significantly below freezing. The Frostban microorganisms acts by pre-empting growth of the natural bacteria that catalyze ice crystal formation thereby protecting the plants from frost damage.

We have produced Frostban by a simple genetic modification of two common, naturally occurring species of bacteria, Pseudomonas fluorescens and Pseudomonas syringae. This modification involves removing portions of the genes that make those strains "ice nucleation active," or "INA+." The

term "ice nucleation" describes the ability of microscopic particles, including dust and bacteria, to serve as catalysts for the formation of ice crystals at temperatures below -10°C. "Ice nucleation active" is a technical classification that refers to specific, naturally occurring microorganisms, including certain strains of P. syringae and P. fluorescens, which can promote the formation of ice crystals at temperatures just below freezing, that is, from -1°C to -10°C. Organisms possessing this ability are called "ice nucleation active" or "INA+."

Scientists at AGS have taken INA+ strains of P. syringae and P. fluorescens that occur naturally on strawberries and deleted from them a portion of the specific gene that gives them the INA+ characteristic. This is the only change we have made. No foreign genetic material has been introduced. No other genes have been altered in any way. The altered bacteria resulting from this small and precise modification are called "INA-" and are identical to the parent strains except for their lack of ice nucleating ability. In general characteristics, these altered strains behave in a manner expected of any naturally occurring INA+ P. syringae or P. fluorescens. Furthermore, they behave in a manner expected of any non-ice-nucleating Pseudomonas. Non-INA bacteria normally constitute the vast majority of bacteria inhabiting a plant surface.

The bacterial species we are working with, P. syringae and P. fluorescens, occur in abundance in nature, colonizing plant surfaces such as leaves and blossoms. These strains do not harm the plants they colonize except that the INA+ strains can cause frost damage to occur at just below freezing temperatures. The particular strains we have chosen to work with colonize strawberry plants and other members of the same plant family. By establishing the INA- altered strains on strawberry plants during the early bloom period, we hope to prevent frost damage by preempting the similar growth of INA+ strains on blooms from reaching their full potential. If the principle works, other similar organisms can be developed to protect other food crops from frost damage and to control other plant pests. Effective frost damage prevention of this type has substantial potential value, as over a billion dollars of crops are lost to frost and freezing each year. We believe this and related products could be of great value in years to come in expanding the world food supply and preventing significant economic losses to agriculture.

B. AGS Applications for Federal Approval for Small Scale Field Testing

AGS has come to a point in the development of Frostban where it must test the product under natural field conditions. The field test that AGS has proposed is a well controlled application of Frostban organisms on strawberry plants in about

an 81 x 81 foot area. The purpose is to test the ability of Frostban to compete with organisms in the natural environment. Two federal agencies have played principle roles in the review and approval of the AGS application to conduct this field test. On March 22, 1984, we notified the NIH Recombinant DNA Advisory Committee (the "RAC") about our field test proposal. As a private company, we were not required to seek NIH approval, but we voluntarily notified the RAC because we were aware of public concern about deliberate release experiments, and we did not wish to go forward without the support of the scientific community and the public confidence RAC approval would provide.

In our application to the NIH RAC, we included information about the proposed test of Frostban and data such as the characterization of strains, pathogenicity (the ability to cause disease), colonization, and competition. The RAC met on June 1, 1984 to evaluate the AGS proposal. The RAC voted unanimously to recommend approval by NIH provided that certain additional monitoring be required during the field test and certain additional data be supplied by AGS prior to NIH approval. AGS was notified of this action by letter dated October 18, 1984. In response, AGS submitted additional data to NIH by letter dated November 15, 1984.

In the meantime, the EPA was considering how it should regulate products of biotechnology under the Federal

Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). EPA issued its Interim Policy on Small Scale Field Testing of Microbial Pesticides under FIFRA on October 17, 1984. The EPA interim policy requires notification of the agency prior to field testing certain microbial pesticides. If the agency determines the field test proposal should be subject to more in depth review, it requires the proponents to obtain an experimental use permit before conducting the test. EPA considers our INA- bacteria to be pesticides because they mitigate frost by competing with the "pest" INA+ bacteria. We were therefore required under the interim policy to notify EPA of our proposed field test of Frostban. Given the need to obtain approval of the field test by EPA, we later withdrew our voluntary effort to obtain approval by NIH.

On November 5, 1984, we formally notified EPA of our field test proposal. The information we supplied to EPA was substantially the same information we had given to the NIH RAC. We furnished additional data to EPA on January 10, 1985 in response to requests for further information. Three different groups within EPA reviewed the initial submission. They were the Hazard Evaluation Division (HED) of the Office of Pesticide Programs (OPP), the Intra-Agency Work Group on Biotechnology, and a special subpanel of the FIFRA Scientific Advisory Panel (SAP). On January 30, 1985, HED issued its

conclusions based on these scientific reviews. While HED stated that the risk of adverse environmental effects was low, they felt that additional data were necessary for EPA to approve the proposal.

Accordingly, on February 1, 1985 EPA notified AGS that it would require AGS to obtain Experimental Use Permits (EUPs) prior to conducting the field test. We were also requested to provide additional data including expanded plant pathogenicity tests, information on the test plot and test conditions, the survival, persistence, and competitiveness of the INA- bacteria, and monitoring plans for detecting offsite dissemination of the INA- products. Accordingly, on July 2, 1985, we submitted two EUP applications and the additional supporting data which we supplemented periodically with follow-up information. HED then conducted further review of the data, as did the SAP subpanel and the intra-agency biotechnology work group.

On August 21, 1985 EPA published a notice in the Federal Register stating it had received our applications and soliciting public comment. EPA also solicited comments from other federal agencies having biotechnology experience and expertise, including USDA, FDA, and NIH. EPA received one comment from the general public. That came from Mr. Edward Lee Rogers on behalf of the Foundation on Economic Trends. Of all the comments received from the public, government agencies, and

science experts, his were the only ones which suggested that the AGS applications should not be granted. EPA thoroughly reviewed and responded to all of Mr. Rogers' comments. On November 14, 1985, EPA approved issuance of the experimental use permits.

C. Data Submissions

I would like to describe for you in some detail the kinds of data we furnished to EPA with our EUP applications. First, we provided a literature review of toxicology considerations. We gave the agency data on the infectivity and pathogenicity of the altered bacteria to target and nontarget plant organisms. For this purpose, we carried out pathogenicity testing of 30 different plant species. No pathogenic reactions were observed on any of the plants receiving the parental or altered bacterial strains. Since these tests have been the subject of some recent controversy, I will discuss them further in a moment. However, I would like now to describe some of the other data we supplied to EPA.

One of the central issues we addressed in our studies involved the potential dissemination of the altered bacteria outside the test plot. We performed a wide variety of studies to get at this issue. For example, we studied the ability of the altered strains to grow on leaves and blossoms of various plant species other than strawberry and found them very poor colonizers of many other plant species. We did note the

ability to colonize various plant species from the strawberry plant family, including certain fruit trees and wild blackberry. This did not surprise us, since the strawberry plant family is the natural host for these bacteria. However, we found conclusively that the INA- strains were not more competitive than natural bacterial strains when growing on test plants. In addition, extensive dissemination studies carried out by AGS scientists and by other scientists on similar bacteria show that the possibility of any of the altered bacteria becoming established on any plants outside the test plot is extremely low. These studies included studies of dispersal through aerosols with the natural strains under field conditions, dispersal of natural strains by insects, and potential survival on plants adjacent to sprayed areas in the field. From all of these studies, then, we were able to conclude that the effect of our altered strains in the environment would be undetectable and negligible. The data from all of these environmental fate studies were provided to EPA and reviewed by their scientists.

In sum, we believe that given the nature of the proposed field test, EPA required, and we furnished, very substantial and comprehensive data in support of the EUP applications. As a result, EPA's issuance of the permits is based upon a careful and thorough risk assessment.

III. RESPONSE TO RECENT NEWSPAPER ARTICLES

Last week, several newspapers carried stories about the tests done by AGS to confirm that Frostban bacteria are not pathogenic to various types of plants. These articles carried a number of unsubstantiated and unattributed allegations about the data AGS supplied to EPA, as well as allegations that one of the tests performed by AGS violated the EPA interim policy on experimental field tests. Because these articles have caused public concern about the quality of the data AGS offered in support of its application, I will address each of the allegations made.

A. Compliance with the EPA interim policy on experimental field tests.

First, let me address the question whether certain tests done by AGS complied with the EPA interim policy. In response to EPA's request for additional data regarding pathogenicity, AGS planned a comprehensive program of tests designed to furnish EPA the data it requested. Many of the tests were conducted simultaneously in an effort to complete the work in time to have the experimental use permits issued for a spring, 1986 field test. All of these tests were conducted in an AGS greenhouse located on the roof of the AGS facilities in Oakland, California with the exception of one series of tests which took place outdoors on the roof. Photographs of the AGS facilities appear in the AGS 1984 Annual

Report. The rooftop facilities are shown on page 5. A large aerial photo has been provided to your staff which shows the location of the AGS facility in relation to the surrounding area.

The purpose of these particular tests was to confirm that the AGS altered bacteria are not pathogenic in several types of fruit trees. In general, these tests consisted of injecting four kinds of material at different sites on small branches of several types of fruit trees. The materials injected included (1) naturally occurring INA+ bacteria suspended in phosphate buffer solution, (2) altered INA- bacteria suspended in phosphate buffer solution, (3) a known pathogenic bacteria suspended in phosphate buffer solution, and (4) the phosphate buffer alone. The trees were observed for up to seven months for the development of pathogenic reactions. Pathogenic reactions were observed only at those sites injected with known pathogens. These reactions were evident within two weeks.

EPA apparently believes that the tests AGS performed outdoors on the roof do not comply with the EPA interim policy on small scale field tests of microbial pesticides. While with hindsight we can certainly understand EPA's interpretation of its interim policy, I would like to explain how AGS interpreted the EPA requirements at the time. The management group responsible for the ongoing development of the Frostban project

was the frost prevention steering committee. This committee convened on an as-need-be basis. The committee consisted of the then President, Dr. Tom Dyott, Director of Product Development, Dr. Douglas Sarojak, the Field Manager and Manager of Regulatory Affairs, Mr. Steve Cull, the Director of Product Research, Dr. Trevor Suslow and a Senior Plant Pathologist, Dr. Julianne Lindemann. The other senior scientific staff and I were usually invited to attend, but our attendance was not mandatory. The principle function of the group was to direct all the activities relating to the development of Frostban as a product, including evaluation of test requirements for submission to the EPA. Soon after the publication of the interim policy, Mr. Cull distributed copies of the policy to the group, though no specific discussions relating to the details of the policy were held at that time. Compliance by those conducting the experiments was implicit. The group carrying out these experiments was aware of the policy, had read it, and believed they were in compliance with the policy in all of the experiments they carried out.

The decision to carry out the pathogencity test on trees on the roof was carried out with the following perceptions. Under the NIH Guidelines for Research Involving Recombinant DNA Molecules, because of the nature

of the genetic change in Frostban, the Frostban bacteria are exempt from any special requirements for physical containment in the laboratory with the exception that NIH must be notified and approve of any "deliberate release" of organisms to the environment. To the extent containment is required for altered bacteria under the NIH guidelines, it involves both physical containment and methodologies and practices designed to minimize the potential for release. The researchers involved in the fruit tree tests had worked with the Frostban organisms for years adhering to these guidelines. Thus their interpretation of the more recent EPA interim policy was influenced by these NIH concepts.

The choice of the outdoor roof top space for the tree tests was a pragmatic one based on the physical space requirements and duration of the experiment. All these trees could not be physically contained within the greenhouses if the other pathogenicity and related experiments were to be conducted at the same time. The EPA was not notified of plans to use the outdoor space because the scientists involved did not interpret the use of the outdoor rooftop area for tree branch injections as a "field test" subject to the EPA interim policy. The proposed spraying of Frostban in an agricultural setting is the kind of "field test" they believed to be subject to

the notification requirements. They believed the inoculation methods to be used in the rooftop tests would minimize any potential for release, and they were confident that the test organisms were not pathogens and therefore would not multiply in the fruit tree tissues. Moreover, they were confident that the tests involving the injection of bacteria into branches of trees located on the roof would not constitute any greater risk of an environmental release than a greenhouse experiment because the injected bacteria would be contained within the plant tissues and the tissues would be sterilized and properly disposed of at the conclusion of the experiment.

In short the experiment was done outdoors on the roof top without prior notice to EPA because the researchers felt that the experiment did not constitute a "field test" that the methodology and physical environment provided adequate "containment" and did not involve a "direct release" of altered bacteria to the environment.

The AGS conclusions regarding the level of containment offered by the method of inoculation and the rooftop location were based on the following facts:

(1) Pseudomonas fluorescens has never been reported as a pathogen of fruit trees. We were, therefore, quite confident that it would be rapidly immobilized within the tree and die. Within the species Pseudomonas syringae all

the pathogenic strains which effect Rosaceous fruit trees belong to a different taxanomic subgroup than the group to which the AGS strains belong. Thus we were confident the AGS P. syringae strain also would be rapidly immobilized within the tree and die.

(2) The bacteria were to be injected into the trees with a hypodermic syringe and not applied to the outside of the tree by aerosol. Thus the vast majority of bacteria would be completely contained within the tree tissues.

(3) The miniscule number of any bacteria which might inadvertently be released onto the soil around the trees or onto the roof surface would rapidly die from dessication, UV irradiation, and generally unsuitable growth conditions.

While AGS believes its researchers acted in good faith in their interpretation of EPA requirements, we do not wish to press for this view of the meaning of "field test" or "containment" as the proper interpretation of the EPA interim policy. We are quite prepared to accept EPA's judgment on the appropriate interpretation of their regulations and to conduct our future work accordingly.

The controversy surrounding the outdoor test did not arise as a consequence of any inadequacy of the EPA interim policy nor as consequence of any conscious disregard of that policy by AGS scientists. The tree

pathogenicity tests took place as a result of a responsible decision made by qualified and cautious people, who interpreted the procedural requirements of the EPA policy with insufficient sensitivity to the importance of having the EPA, acting on behalf of the public, share in making even the most cautious decisions with them.

B. Validity and Realiability of AGS Experimental Data

The issue whether performance of the outdoor tests complied with the notification requirements of the EPA interim policy does not affect the quality of the data the tests supplied. AGS scientists stand behind the results of our research on the pathogenicity of both the altered and parent strains involved in our work. The methods we used, including the conditions under which the tests were performed, were based upon a thorough survey of the scientific literature, on personal communications with scientists who had performed and published the results of similar studies and the considered opinions of our two senior plant pathologists who collectively have more than 20 years of experience working with pseudomonas species. Moreover, in order to assure that the test conditions were conducive to a pathogenic response, the tests for pathogenicity were performed using both positive and negative controls. I would like to take a moment to elaborate on the nature of positive and negative controls,

since they provide scientists with proof of the validity of their experimental results.

The "positive control" consists of performing the experiment with an organism known to be pathogenic. It is used to confirm that the conditions under which the tests are performed are conducive to the development of a pathogenic reaction. If no reaction occurs in response to an organism known to cause one, then the test conditions are brought into question. If such a reaction does occur, it confirms that the test conditions are conducive to infection by the positive control organism and similar organisms if they are pathogenic.

The "negative control" consists of injection of the buffered solution by itself. This is done to confirm that the solution in which the test organisms are suspended does not itself cause a reaction. If a reaction does occur, it can be compared with reactions caused by the positive control to distinguish the appearance of a pathogenic reaction from the appearance of a reaction to the buffered solution and the physical wound caused by the injection. The reaction to the injection is called a "wound response."

Recent newspaper articles have alleged that cankers developed on trees injected with the altered bacteria. A canker is a local infection characterized by

sunken water soaked tissue around a wound site containing multiplying pathogenic organisms. The fruit trees used in the outdoor tests were observed for up to seven months for symptoms of pathogenic reactions, including cankers, at the injections sites. None of the sites receiving the genetically altered bacteria developed any pathogenic reactions. Cankers, however, did develop at sites injected with known pathogens. This confirms that the rooftop conditions were conducive to the growth of this and similar pathogenic organisms. At a few injection sites, non-pathogenic reactions typical of a wound response were noted. In the judgment of our senior plant pathologists, these reactions were clearly distinct from cankers. These reactions were observed at some sites injected with both the natural INA+ bacteria and the AGS altered bacteria and at some sites receiving only the buffered solution. Because this reaction was observed in response to the buffered solution alone, we concluded that the reaction at the test sites was not caused by the altered bacteria. As a further test of this conclusion, tissues showing the wound response were tested for the presence of altered bacteria. No viable altered bacteria were found. This confirmed our initial conclusion that the altered bacteria did not cause the reaction observed.

Recent newspaper articles have also alleged that "bacteria-burdened air" probably escaped from windows in

the greenhouse roof. As I mentioned earlier, all of the other pathogenicity tests and all tests for survival, growth, and competition were performed in the AGS greenhouses located on the roof of the AGS facilities. These tests involved inoculation of a diversity of plants with the same treatments mentioned above in regard to fruit trees in order to confirm that neither the INA+ bacteria nor the INA- bacteria were pathogenic on plants. The inoculation procedures used in the greenhouse pathogenicity tests included injection procedures and in some cases swabbing. Such procedures do not create aerosols. In some pathogenicity tests, and in all colonization studies, aerosol producing inoculation methods were used. These procedures, however, were performed while the plants were located inside a plexiglass inoculation chamber. This box was closed for a period of time after spraying, allowing any airborne bacteria to settle. The chamber was swabbed down with alcohol after this procedure. As a general matter, under these circumstances, the bulk of the bacteria are located on the plant tissue. Any bacteria in the air would be expected to occur in miniscule numbers and die rapidly. This was confirmed experimentally during the development of these procedures by the presence of uninoculated control plants in the greenhouse. These plants were

tested for the presence of test bacteria on the blossom surfaces at the time of the tests. Neither natural or genetically altered bacteria were found on the uninoculated plants, demonstrating the minimal quantity of bacterial drift in the air even within the greenhouse. During the duration of the experiment, the numbers of bacteria removed from plants by wind currents created by heating and cooling units within the greenhouse would have been extremely small. Data demonstrating the small numbers of these types of bacteria removed from plants by wind in the natural environment are contained in the AGS EUP application.

It is important to note that EPA has not developed any guidelines concerning the level of containment required for tests not subject to its small scale field test notification requirements. NIH has developed guidelines for recombinant DNA research which have been utilized for many years as the standard for containment in both academic and commercial laboratory research. The NIH guidelines recommend different levels of containment for different altered organisms depending on the perceived risks involved. Because of the nature of the genetic alterations in Frostban, these organisms are not subject to any special containment requirements by the NIH guidelines. Good microbiology laboratory practices

are adequate. It would be prohibitively expensive and unnecessary to provide absolute (if that's possible at all) containment for every procedure involving genetically altered organisms. The approach of the NIH guidelines appears to provide adequate protection at a reasonable economic cost.

A third allegation made in the recent newspaper stories was that the pathogenicity tests performed by AGS are not valid because of the lack of proper temperature controls. The pathogenicity tests conducted in the greenhouse were conducted under controlled temperature and moisture conditions. Temperature is automatically controlled in the greenhouses by air conditioners and heaters operated by appropriate heat sensors. For those experiments requiring constant surface moisture, plants were placed under mist nozzles which were automatically controlled by a leaf wetness simulator. In addition, the conditions under which the tests were performed were monitored by the use of a positive control. As I explained earlier, the positive control is a known pathogenic organism similar to the test organism. If the positive control shows symptoms of disease, it indicates that the test conditions were appropriate. In fact, the use of a positive control strain would validate tests done in a facility which lacked any temperature control.

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Finally, it should be noted that the inoculation procedures used in the tests were reviewed by the EPA's Scientific Advisory Panel. The procedures and results were presented before scientific colleagues at meetings of the International Congress of Plant Pathogenic Bacteria and the American Phytopathological Society without ever being subject to criticism.

IV. LOCAL COMMUNITY CONCERNS

In closing, I would like to turn my attention to the concerns expressed by the local citizens of Monterey County, the county in which the field test is to be carried out. I understand that Mr. Sam Karas, Chairman of the Monterey County Board of Supervisors will be testifying later in the hearing about the local community's concerns, and so I will be brief. AGS has learned a great deal over the past several weeks about how the public perceives our work and the prospect of a release of genetically engineered organisms. While most recognize the enormous potential benefits of biotechnology, there is a general lack of knowledge about microorganisms and a deep concern about the potential risks involved. This is understandable, and we scientists must work harder to help the public learn more about what we do, so that the public can better discern along with us

the difference between those activities which may present significant risks and those that present only negligible risks, if any. Public education has not kept pace with our science, and the scientific community and industries that use biotechnology must attend to this if we are to continue to advance toward useful and beneficial applications of the science.

In addition, the public should be given adequate opportunity to participate in decision making on biotechnology issues. AGS is hopeful that EPA and the other federal agencies having jurisdiction over biotechnology products will review their procedures to assure that any local communities affected by proposed actions are given early notice and a full opportunity to comment before the action is taken. We also plan to do a better job ourselves of establishing communications with the communities in which we do field test work. While we have gotten off to a rocky start in Monterey County, we are confident that with efforts on both sides, we can resolve any concerns the County may have, and we look forward to good relations with the County in the future.

* * *

In conclusion, I want to thank you for the opportunity to speak before this Subcommittee today.

There has been a great deal of misinformation in the newspapers about our field test proposal, and this hearing has provided us an excellent opportunity to correct any misunderstandings. AGS appreciates the opportunity to review these issues with you and we look forward to working with federal, state, and local authorities to assure that our work meets all appropriate standards for biotechnology research.

Mr. VOLKMER. Thank you very much, Dr. Bedbrook.

I have quite a few questions here, and we will try to get through them.

As I understand it, your original application from Advanced Genetic Sciences to EPA for a permit stated that all tests will be conducted at sites remote from major fruit areas and at sites remote from major crop production areas. Is that correct?

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. And, in fact, the test site you were proposing is located near a residential area where other crops in the strawberry family, such as almonds, apples, pears, and apricots are grown, is it not?

Dr. BEDBROOK. That is correct, the field test. Yes, sir.

Mr. VOLKMER. Yes, the field test site.

Dr. BEDBROOK. Yes.

Mr. VOLKMER. You do not believe that the field test site necessarily has to be remote, then?

Dr. BEDBROOK. On the issue of the requirements for the remoteness of the site, I am not clear about that.

Mr. VOLKMER. All right. Then, we will take it up more with the EPA.

Dr. BEDBROOK. What I should say about our view of the appropriateness of the site was based on our knowledge of the ability of these organisms released in the test to drift. We felt that, given the extensive data we had in relationship to the ability of these organisms to drift, that the site was sufficiently remote from any other crops or residences to exclude the possibility of large numbers of bacteria reaching such areas.

Mr. VOLKMER. This is going to be the first field test of any type of microorganism, is it not, here in the United States?

Dr. BEDBROOK. That is correct, Mr. Chairman.

Mr. VOLKMER. I think we should all remember that. And didn't EPA recommend that the tests be done in a remote location?

Dr. BEDBROOK. Sir, I am not sure about that issue, I am sorry.

Mr. VOLKMER. All right. Now, who within the company knew where the test site would be located?

Dr. BEDBROOK. The field manager, the president of the company at that time, and the Frostban steering committee which is the management group controlling the project.

Mr. VOLKMER. Who presently is the owner of the site where the field test will be taking place?

Dr. BEDBROOK. I have the interest of protecting the owner, Mr. Volkmer. We will be very happy to——

Mr. VOLKMER. Let me rephrase the question just for my own purposes for what I would like to know because of things I have heard and things like that.

Dr. BEDBROOK. Yes.

Mr. VOLKMER. Let me ask you this: without naming any names, if the owner of the test site is also either an employee or stockholder and/or affiliated with Advanced Genetic Sciences, Inc?

Dr. BEDBROOK. The owner of the property is indeed one of us.

Mr. VOLKMER. All right. That satisfies my question.

Now, in your application to EPA, you stated that "applicators will wear protective clothing, including whole body waterproof

clothing, spray suits, hats, gloves, and boots. Goggles and a NIOSH approved respirator will also be worn." Is that correct?

Dr. BEDBROOK. That is correct, sir.

Mr. VOLKMER. You know the site is in a residential area. You are going to see these people out there. We in Missouri have seen them with dioxin, OK? You are going to have the neighbors out there seeing these people spraying stuff around the strawberry patches, and they are not going to have those kind of suits. Can you see some possibility of concern by those people?

Dr. BEDBROOK. I can certainly see a perception that would indicate that this was something dangerous that must be going on here.

Mr. VOLKMER. Yes.

Dr. BEDBROOK. But I can assure you, sir, that the reason for wearing these suits and so on was at the advice of the regulatory people as an indication of our caution rather than an indication of the risk involved. But I can certainly understand the potential for the perception, yes, sir.

Mr. VOLKMER. Right. Now, there is no information given to the local community, the people of Monterey and that area, about the field test. Is that correct?

Dr. BEDBROOK. By the company?

Mr. VOLKMER. Yes.

Dr. BEDBROOK. That is correct, sir. We notified the State and, as I understand it, the State notified the county Ag commissioner.

Mr. VOLKMER. OK. Now, in your permit application, you stated that the "pathogenicity of our strains can only be surmised from the reaction of inoculated plants." Is that correct?

Dr. BEDBROOK. That is correct, sir.

Mr. VOLKMER. And then you stated that "plants were incubated on a greenhouse bench and/or under moist conditions at 21 plus or minus 5 °C as recommended by reference publications." Is that correct?

Dr. BEDBROOK. Yes, sir.

Mr. VOLKMER. Is that correct?

Dr. BEDBROOK. That is correct, yes.

Mr. VOLKMER. And then you go on to state that for pathogenicity tests, "all annual plant species were grown from seed in a greenhouse."

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. "Perennials such as oleander, almond, cherry, and pear were also used." Is that correct?

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. Now, the perennials, where were they used? In the greenhouse?

Dr. BEDBROOK. Yes, sir.

Mr. VOLKMER. The almond, cherry, and pear were used in a greenhouse?

Dr. BEDBROOK. I am sorry, sir. The pathogenicity tests for the trees, as I was saying before—I am sorry—were carried out on the rooftop.

Mr. VOLKMER. Outside of a greenhouse.

Dr. BEDBROOK. Yes; that is correct.

Mr. VOLKMER. Do you consider your greenhouse a contained facility?

Dr. BEDBROOK. Yes, sir.

Mr. VOLKMER. Does it have ventilation to the open air?

Dr. BEDBROOK. It does, indeed.

Mr. VOLKMER. Where does the water from your greenhouse go?

Dr. BEDBROOK. With respect to drainage, we have two types of greenhouses, one in which there is no——

Mr. VOLKMER. Excuse me, Doctor. Address the part of the greenhouse or all of it where the tests were done as far as the ice-minus bacteria.

Dr. BEDBROOK. Yes, sir. That does mean considering a couple of greenhouses, but the precise or the ultimate location of the drainage in our greenhouse would be the normal effluent system.

Mr. VOLKMER. Which would mean back into the city sewers or that type of thing?

Dr. BEDBROOK. Yes, sir. That is correct.

Mr. VOLKMER. And that means that some of the bacteria, if it drains off, would drain into the city sewer system?

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. And do you feel that your greenhouse complies with the NIH-RAC guidelines for containment conditions of greenhouses and growth chambers?

Dr. BEDBROOK. The NIH guidelines do not specify any requirements in relationship specifically to greenhouses. What I would like people to understand and the committee to understand is that containment in the sense adopted by the NIH relates to two things. It relates to the physical containment, and it relates to containment afforded by adopting certain methods and procedures.

In my view, the greenhouses that we have comply with the containment required for, say, a P-1 facility as designated by the National Institutes of Health. Under those terms, Mr. Chairman, there is no requirement, for example, for a lack of ventilation system that is exposed to the outside.

Mr. VOLKMER. And you feel that there is no requirement that any effluent from the greenhouse should be contained?

Dr. BEDBROOK. My feeling is that one should adopt practices that minimize the chance that large numbers of bacteria would go down the drains, and there are various procedures one can do to adopt that.

Mr. VOLKMER. Let me ask you this. As I understand your procedure, you were brushing on or swabbing on the plants in the greenhouse and, simultaneously, in order to preserve the moisture needed, there was a mist from city water coming down—I am not going to get into that in the quality of the tests—but coming down onto the leaves, et cetera. Are you saying that none of that bacteria from the leaves, et cetera, was then going to escape into the water that is dripping off the leaves and going down?

Dr. BEDBROOK. Based on the available data which is really quite extensive from the literature on plant pathology, the expectation for the numbers of bacteria coming from such humidifiers would be miniscule. In other words, there is no free water on the——

Mr. VOLKMER. No, no. I don't want to address that. I want to address the water that comes off the leaves and goes down into the drain and down into the city.

Dr. BEDBROOK. Yes. What I am doing is attempting to address that very water.

Mr. VOLKMER. All right.

Dr. BEDBROOK. Water coming down from a mister onto the floor of the greenhouse, in order to get into the drains before bacteria would be decontaminated or die, would necessitate a free flow of water. What I am saying is that the number of bacteria reaching the water supply—sorry—the sewerage system would be miniscule while adopting these procedures.

Mr. VOLKMER. Now, was this a P-1 facility or hoping to be a P-1 facility? What you basically said was that you felt that it qualifies as a P-1 facility.

Dr. BEDBROOK. My feeling is that the greenhouse fits within the general criteria of P-1. I must stress that NIH does not specify what constitutes levels of containment of greenhouses.

Mr. VOLKMER. Do they not require air filters for filtration so it doesn't go right out into the air, and do they not require water sterilization?

Dr. BEDBROOK. P-1 containment, to my knowledge, and I could be wrong on this, but, to my knowledge, does not require any particular filtration procedures of air leaving the room.

Mr. VOLKMER. Now, on the tests that were done on the roof, I would like to ask you something that I just don't understand. In order to make the tests valid as far as the ice-minus potential of your product and pathogenicity in the greenhouse, you did it to maintain a temperature of 21 plus or minus 5 °C plus the moisture and everything. Yet, out here on the roof during the time of day, those things didn't exist, did they?

Dr. BEDBROOK. Sir, with respect to conducting pathogenicity tests, one has to not only consider the pathogen or the potential pathogen, but one also has to consider the organism which is being the recipient of the disease. Relatively high levels of humidity are conducive to optimizing the potential for growth of this pathogen.

Mr. VOLKMER. Correct.

Dr. BEDBROOK. The experiments with trees present a slightly different situation. I am not a plant pathologist by training, but as I understand it, the requirements for humidity and so on are less important for those experiments.

What I want to say about the validity of the experiments in terms of demonstrating that the conditions of growth were adequate in the tree experiments was the use of positive controls of using known related pathogenic species, pathogenic strains—I am sorry—to show that the conditions were indeed conducive to those plants.

My senior plant pathologist assures me that the reason for, in his perception, the principal reason for conducting the tests on the more herbaceous types of plants in the greenhouse was more for cultural reasons, I mean, the culturing of the plants reasons than in relationship to his perceived requirement for a conducive growth condition. Plant pathologists recognize the positive control as being

the most important criterion for saying whether or not a condition is conducive to a pathogenic response.

Mr. VOLKMER. If I understand what you are telling me, no matter what the temperature or the humidity of the air is, if the positive control group does show pathogens, therefore it is a valid experiment. Is that what you are telling me?

Dr. BEDBROOK. That is the most important criterion recognized by plant pathologists, yes.

Mr. VOLKMER. Now, prior to—you did not, or did you, notify the EPA that you would be conducting these pathogenicity tests on the roof in the method that you were doing it prior to doing it?

Dr. BEDBROOK. We did not notify the EPA of the experiments on the roof with respect to pathogenicity tests in trees because the people who conducted the experiment did not perceive that as a release experiment.

Mr. VOLKMER. All right. Well, we will get into that later with the EPA and see what they have to say about that.

Did you use any of the results in order to get your field test approval?

Dr. BEDBROOK. Yes, sir. We used the results from the pathogenicity tests done on trees on the roof as part of our submission for EPA approval for the EUP. Yes, sir.

Mr. VOLKMER. Were the methodologies in the conducting the tests appraised to EPA in advising them fully of the data started, how it started, the number of trees, the description of the various types of trees, the numbers of trees or kinds of trees that got the positive pathogen, the ones that got your bacteria, the ones that got the neutral without any bacteria? Were they given all that information?

Dr. BEDBROOK. The types of trees involved in the experiment were given, and the general methodological methods for the procelures were given, yes.

Mr. VOLKMER. Now, even though in the interim policy guidelines for FIFRA, EPA requires these to be held in a laboratory or containment facility?

Dr. BEDBROOK. Yes, sir.

Mr. VOLKMER. Was EPA ever advised that these tests that were done on the trees were done in the rooftop atmosphere?

Dr. BEDBROOK. The EPA was never advised that these tests were done on the roof.

Mr. VOLKMER. Were they ever advised that these tests were done outside of a laboratory or containment facility?

Dr. BEDBROOK. No, they were not.

Mr. VOLKMER. Why?

Dr. BEDBROOK. I sincerely believe that there has been no deliberate violations of the guidelines because there has been no environmental release. We felt we were meeting EPA guidelines by containing these organisms by considered microbiological practice. In hindsight, we can certainly see EPA's view and that there has been a violation of their interim policy.

The understanding of our interpretation of containment in this experiment was a function of several years of working with these organisms under the NIH guidelines which require no specific physical containment for this organism but, rather, good microbio-

logical practice. So, what we were doing, then, was attaching a great deal of importance to good microbiological practice in relationship to containment of these organisms.

Mr. VOLKMER. Do you believe that due to the fact that we now have it out in the open how the rooftop testing was done that EPA should go back and review this data to determine whether or not what you say is accurate and what your plant pathologists say is accurate as far as the testing being qualified to meet the guidelines?

Dr. BEDBROOK. I am sorry. Could you repeat the question?

Mr. VOLKMER. The thing is, what I can't see is you submitted this data——

Dr. BEDBROOK. Yes.

Mr. VOLKMER. To EPA——

Dr. BEDBROOK. Right.

Mr. VOLKMER. In order to get the EUP.

Dr. BEDBROOK. Yes.

Mr. VOLKMER. But you didn't tell them the full story.

Dr. BEDBROOK. I think it is worthwhile just mentioning that it is not typical practice—I want to put the review of the data in a timeframe, as well. We submitted the original methods and the original data that we had accumulated in greenhouses at one point in time. The EPA came back to us and asked for other tests, including trees. What we then did was to gather data through an extensive research program on 30-odd species and put that data together without amending adequately the methods to specify that tree tests had been done on the roof.

This was an omission. What I am saying is that it is not typical in the presentation of scientific methods to define the specific location of an experiment unless that location is pertinent to the outcome of that experiment.

Mr. VOLKMER. But EPA does require that tests be conducted in a laboratory or containment facility. There has to be some reason for that.

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. And the rooftop didn't qualify for that. I think we have to admit that.

Dr. BEDBROOK. As I said, I feel that in hindsight we can see the EPA's position on that, definitely.

Mr. VOLKMER. You are not saying that the tree is a containment for microorganisms, are you?

Dr. BEDBROOK. Yes; I am saying that the woody tissue of the tree is a containment for a microorganism that does not replicate and proliferate within that tree. We had a body of evidence that this was not going to happen. Therefore, we felt that the tree did indeed constitute a containment for the bacteria by virtue of the procedure.

I would like to explain that the people that are conducting these experiments have been working under the guise of a set of regulations from the NIH which emphasizes the importance of procedural issues in affording containment. It was in this context that we interpreted the practice that we carried out to be a containment.

Mr. VOLKMER. But you did not go to NIH or to EPA and ask them their opinion as to whether or not this would be considered—in other words, the tree and inoculation—a containment.

Dr. BEDBROOK. I thoroughly agree with you that we should have asked for—with hindsight—that we should have asked for notification to carry out the tree experiments, in hindsight.

Mr. VOLKMER. Can you tell me basically—give us a brief description of the methodology of the inoculation of the trees that took place on the rooftop?

Dr. BEDBROOK. An approximate description? Yes, sir.

Mr. VOLKMER. Yes.

Dr. BEDBROOK. The method is to contain within a—place into a syringe—and I am not exactly sure how that is achieved, but normally it is done by drawing a solution of the bacteria up into the syringe. In this case, the amount of liquid is approximately 0.05 ml or a little less than an average-size drop. Then, that is placed under or through the tissue into a young branch and injected into the branch.

Mr. VOLKMER. And, as I understand it, there were three or four different types. You had the positive pathogen, and then you had a solution of your own ice-minus bacteria. There were two different types of those, though, weren't there?

Dr. BEDBROOK. That is right. There were two different species of bacteria, and then there were the two different altered derivatives of those two types. There was the known pathogen which was another *Pseudomonas syringae,* and there was the phosphate buffer solution which was the negative control.

Mr. VOLKMER. All right. Now, how many people actually worked on putting the injections, injecting the different solutions into the branches of the trees?

Dr. BEDBROOK. The experiments were conducted by a technician under the guidance of one of our senior pathologists who was in consultation with our senior pathologist.

Mr. VOLKMER. In other words, you had only one technician who was doing all the syringe injections?

Dr. BEDBROOK. Of the trees. Yes, sir.

Mr. VOLKMER. And then he had a direct supervisor?

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. And then that person had a direct supervisor?

Dr. BEDBROOK. That is true.

Mr. VOLKMER. And during all these experiments there was only one technician, the same person?

Dr. BEDBROOK. During the course of the tree experiments, one technician was responsible for the actual injections. That is correct.

Mr. VOLKMER. Now, did that person who was making these injections also have a duty to observe whether any wounds or cankers occurred on the trees?

Dr. BEDBROOK. That person was responsible for observations on the trees—that is correct—as was his supervisor.

Mr. VOLKMER. And I would assume that they made notes of all their observations, did they not?

Dr. BEDBROOK. They would have made observations and made notes of their observations. That is correct. So, the technician

would take down his observations and confer with his supervisor who would review any observations that he made.

Mr. VOLKMER. Do you know whether or not any of the trees, prior to the beginning of the experiment, had any natural cankers?

Dr. BEDBROOK. I don't know that for a fact.

Mr. VOLKMER. How many trees received the *Pseudomonas strain,* the positive, to cause the cankers?

Dr. BEDBROOK. I only have a general description of the experiment. There were a total of, I believe, seven species of trees inoculated. Approximately four trees were inoculated with each type of—there were multiple inoculations done to approximately four or five trees in each condition.

Mr. VOLKMER. You don't have the records of your testing here with you, do you?

Dr. BEDBROOK. No; not on me, sir. What I can tell you is that the total number of trees involved in all of the experiments was in the order of 50. There were multiple inoculations made. What I have done is read the instructions given to the technician for the experiment, and what was asked for was to have four replications of multiple inoculations for each condition. So, since there were a total of 6 conditions, that would make 42. The person that actually did the experiment carried out more than four in some cases and less than four in others.

I don't have the precise numbers, but that is approximately what was done.

Mr. VOLKMER. Would you have certain branches on the same tree being inoculated with one of the types of ice-minus which is, I guess, the *Pseudomonas syringae* or the *fluorescens* and then also get a *Pseudomonas* positive pathogen inoculation on the same tree?

Dr. BEDBROOK. The same tree could be inoculated with more than one source. In other words, there could be one branch that was testing the INA-minus strain or the altered strain and a separate branch on the same tree that was assaying the regular pathogen.

Mr. VOLKMER. Did you give a positive on every tree? Let me ask you that.

Dr. BEDBROOK. I don't know the answer to that question, sir.

Mr. VOLKMER. I have before me a copy of the data that you submitted in support—to EPA—in support of these tests. It is hard for me to figure something out here. I see a Prunus dulcis which I understand is a form of apricot tree. Then I see a Prunus armeniaca or Blenheim behind it which I understand is a Texas mission almond, and neither one of those shows a positive, pathogen positive, control, in other words, no canker. Is that correct?

Dr. BEDBROOK. If you are asking the question were positive controls carried out for all of the species, the answer is no. The availability of *Pseudomonas syringae* pathogens of this type limited the extent of the positive control.

Mr. VOLKMER. Then I am assuming that there probably was not a positive pathogen injected into those trees. Is that correct?

Dr. BEDBROOK. You are correct in assuming that, yes. So, what the positive means then in that column, in every case that positive controls were done, positive responses were obtained.

Mr. VOLKMER. As they made these experiments, like I said, they kept notes like a log. They would keep notes of what they saw, what they injected?

Dr. BEDBROOK. An observational log, yes.

Mr. VOLKMER. How did they keep track of the branches? Did they mark them in any way?

Dr. BEDBROOK. The branches were marked, yes.

Mr. VOLKMER. How were they marked?

Dr. BEDBROOK. They were marked with tags.

Mr. VOLKMER. What has happened to the notes and logs that were used by the technicians and their supervisors?

Dr. BEDBROOK. They are retained in our files.

Mr. VOLKMER. How often would you say that the trees were checked for wounds or cankers?

Dr. BEDBROOK. I discussed this specifically with the supervisor of the experiment, and she told me that it was approximately weekly observations that were made of the trees.

Mr. VOLKMER. And how many sets of these observation notes would there be?

Dr. BEDBROOK. There would be a minimum of two. Do you mean in the organization?

Mr. VOLKMER. Yes.

Dr. BEDBROOK. There would be at least two and now more because we have been requested for copies by the EPA.

Mr. VOLKMER. The EPA has requested copies.

Dr. BEDBROOK. Yes.

Mr. VOLKMER. I want to know the contemporaneous sets made when the person made the observation.

Dr. BEDBROOK. Yes; I think I understand what you want. What I mean, sir, is that the EPA is looking into the data pertaining to the pathogenicity tests. That was what I was talking about.

Mr. VOLKMER. If a tree, which has been inoculated with one of your bacteria, let's say, S-203, and that is a *Pseudomonas syringae,* and it would have a wound and sap would start coming from it. Would that release any of the bacteria?

Dr. BEDBROOK. When trees are inoculated in this way, sap does emanate from the wound site over a period of days to weeks. A large amount of sap would be about a drop's worth.

Mr. VOLKMER. They leak sap for maybe 1 week, then?

Dr. BEDBROOK. Over a period of days to 1 week or so, yes.

Mr. VOLKMER. Were any of them ever tested, in other words, the wound and the sap ever tested for the presence of either *Pseudomonas syringae* or *Pseudomonas fluorescens?*

Dr. BEDBROOK. Whenever any kind of observation was made that was suggestive of a response, then ultimately that tissue was analyzed for the presence of bacteria. I think it is important, as a matter of how one tells whether or not an organism is pathogenic, to note that a response per se is not sufficient. Obviously, if one was to look at the notes of these experiments, one would find that there were certain responses to the phosphate buffer control, for example.

In order to fulfill what is known as Koch's postulate in relationship to finding a pathogen in relationship to a symptom, it is necessary to not only observe a symptom but also to establish that the

bacteria or the organism, be it a fungus, bacteria, or what have you, is multiplying and thereby causative of that symptom.

Mr. VOLKMER. And you went ahead and made those tests as the events occurred. Is that correct?

Dr. BEDBROOK. There were tests done, as I understand it, with respect to any responses obtained from the deletion mutants, which are really the test organism in this experiment, if any spurious response was obtained from injection with those organisms, they were ultimately extracted. There was an attempt to recover those organisms from that tissue, and we failed to ever see any.

This is how we defined, or part of how we defined, that these were not pathogenic to these species.

Mr. VOLKMER. Did you inform the EPA about the sap and the wounds from the trees?

Dr. BEDBROOK. In the methodology of the experiment?

Mr. VOLKMER. Yes.

Dr. BEDBROOK. No; to my knowledge, no.

Mr. VOLKMER. In other words, you did not consider it substantive to the tests?

Dr. BEDBROOK. No; I think it is a typical response from an injection. It is not substantive to whether or not we have put the bacteria into the tissue, if that is what you are asking.

Mr. VOLKMER. It is not substantive to the question of pathogenicity either, then.

Dr. BEDBROOK. I believe not, no. I mean, of course, as with any other injection, there is a variable response to injection, as with injecting a human being, for example.

Mr. VOLKMER. Did you apply to EPA to test both the bacterial species, *Pseudomonas syringae* and *Pseudomonas fluorescens?* Is that correct?

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. And is it true that some strains of *Pseudomonas syringae* can be pathogenic to plants but not humans?

Dr. BEDBROOK. That is true.

Mr. VOLKMER. And we already covered that both species were injected into trees. Is that correct?

Dr. BEDBROOK. That is true.

Mr. VOLKMER. And you are telling us that your evaluation of the sap on the trees did not contain any species of this bacteria?

Dr. BEDBROOK. If you are asking me—I thought you were asking me about the wound site rather than the sap per se. To my knowledge, no attempt was ever made to cover the sap. The sap is a viscous, sugary emanation very difficult to sample. I thought you were asking me about the wound site and the tissue relationship to the injection. The sap, per se, was not assayed.

Mr. VOLKMER. It was only out of the wound itself then that you——

Dr. BEDBROOK. The tissue surrounding the area of injection was analyzed, yes.

Mr. VOLKMER. OK, not the sap then. Did you ever see birds or insects up there around the trees?

Dr. BEDBROOK. I never observed either insects or birds around the trees, sir.

Mr. VOLKMER. I am just wondering if there were some up here that got into the sap.

In your permit application, you state that: "a reaction was rated pathogenic if the tissues became water soaked or if a canker, tumor, or necrotic lesion developed or if the tissues rotted, softened, or wilted." Is that correct?

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. And in your permit application table 1g, the data on pathogenicity shows and it is further stated that "no pathogenic reaction, infectivity, or phytotoxicity was evident in these tests" on either the parental or ice-minus derivatives. Is that correct?

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. And that conclusion was based in part on data you obtained from the rooftop tests, is it not?

Dr. BEDBROOK. That indeed was part of the data contributing to those conclusions.

Mr. VOLKMER. Did you find any cankers on the trees injected with variations of the ice-minus bacteria?

Dr. BEDBROOK. I talked specifically to my senior pathologist on this issue, Mr. Chairman. He and the person who was supervising the experiment assured me that no canker that is indicative of a *Pseudomonas*-type infection was ever observed on any of the material involved in this experiment, unequivocally not.

Mr. VOLKMER. Now, what do we mean by canker having *Pseudomonas* infection?

Dr. BEDBROOK. Obviously, "canker" is a fairly general term.

Mr. VOLKMER. Correct.

Dr. BEDBROOK. But in relationship to this particular disease, it means a water-soaked area surrounding the area of injection which contains multiplying bacteria. One can evaluate a response observationally, and, at the level of observation, the pathologist that I talked to assured me that no such response was ever observed in these experiments. So, that was the first point.

The second point relates to the multiplication of organisms in those cankers or in those potential cankers. No multiplication was ever observed in any area surrounding the injection site by the *Pseudomonas syringae,* or *Pseudomonas fluorescens* normal, or altered strains. The only true cankers, the only symptoms that were indicative of a disease process to my senior pathologist occurred in the positive controls, namely, with known pathogens of those trees.

Mr. VOLKMER. What you are telling me—you aren't telling me, then, that there were no cankers on the trees or on the branches?

Dr. BEDBROOK. I am telling you, from the observational point of view of the experienced pathologist, no, there were no cankers.

Mr. VOLKMER. But there were cankers but they were not attributed to the——

Dr. BEDBROOK. No; I cleared this point with the pathologist very carefully because I think it is a very important one in relationship to the data.

Mr. VOLKMER. I think it is very important.

Dr. BEDBROOK. Let me go back. The definition of a canker to me is a rather general one. To an experienced plant pathologist, and I am talking about collectively, between the two, people 20 years of experience with working with these organisms, a canker in rela-

tionship to a *Pseudomonas* disease has a very specific observational meaning.

Mr. VOLKMER. That observational meaning is that it is what, draining constantly or what?

Dr. BEDBROOK. No; it is not so much draining as a consequence of being water soaked. It is as if the tissues collapse so that there is—it is like a waterlogged piece of tissue. Within that waterlogged tissue, there are replicating, multiplying organisms.

Leaving aside the multiplying organisms, just the observational characteristics of what they classify as a canker was never observed on any of these injections relating to the recombinant or the strains from which they were derived.

Mr. VOLKMER. If you had found cankers, it would indicate a pathogenic reaction according to criteria found in your application, would it not?

Dr. BEDBROOK. In order to demonstrate that a pathogenic reaction has occurred, it is not sufficient just to observe a canker, but you would also want to look for multiplication in the case of an unknown. In the case of an unknown, you really want to demonstrate that the organism that was causing the symptom was the organism that you thought was causing the symptom.

Mr. VOLKMER. If you—in other words, if there had been a canker on a branch which had been inoculated with either the *Pseudomonas syringae,* or the *fluorescens,* or one of the derivatives, then that should have been reported, am I right, to EPA?

Dr. BEDBROOK. If a symptom indicative of a disease had been observed and was demonstrated to contain the multiplying organism, it should and would have been reported.

Mr. VOLKMER. So, if you just saw a canker on it, it is not necessarily a negative reaction. That is what you are telling me.

Dr. BEDBROOK. Since "canker" is a general term, I would have to say that it would be if my senior pathologist came to me and said that is a canker, I would say then that must be as a consequence of there being a disease.

Mr. VOLKMER. All right. Now, I have a copy of a synopsis of information that we have been provided on the tests on the rooftop, and I am going to furnish you with a copy of that. We also have been provided with a photo of what I have been told is a canker. I have also been told that it appeared on, if my memory serves me right, the Prunus armeniaca tree, the Texas mission almond, which you have submitted in your data to EPA is as providing no canker. It didn't have one on the positive control on the sheets that you show. Therefore, it was not inoculated with positive.

Dr. BEDBROOK. I can only say, sir, I firmly believe the——

Mr. VOLKMER. I am not saying—I am just saying this was provided. I just want to know if you have any information regarding it. If not, all I plan to do is let EPA look at it. They are looking at your full thing, and let them look at it.

Dr. BEDBROOK. To my knowledge of the information concerning these tests, the most reliable source of it would be from the company. I think it is quite possible that an ex-employee would have knowledge of the experiment and can provide it through an alternative source.

All I need to say or all I want to say about the results of the experiments submitted to the EPA is that all of the experiments were considered by senior pathologists with a vast amount of experience in these diseases. They concluded through their own observations that there were no diseases caused by these modified organisms, and I am satisfied with that.

Mr. VOLKMER. Does the photograph, at least so we get something, does that appear to be a canker?

Dr. BEDBROOK. I would have to consult with a pathologist to make that observation.

Mr. VOLKMER. Do you have one available? If not, we will let it go.

We will have EPA. They will be testifying, and we will be discussing this with them. Also, the information we have been provided will be provided to EPA. All we are trying to do is to make sure that everything is done according to Hoyle. That is all we want done, and if you have done that, you have nothing to worry about.

I have concluded. I will now turn the questioning over to the gentleman from California, Mr. Packard.

Mr. PACKARD. Thank you, Mr. Chairman.

I may review some things that you have already answered, either in your testimony or in questions, just for review purposes. So, if there are some duplications, please forgive me.

Why did you perform the experiment in the beginning? What were your objectives?

Dr. BEDBROOK. I am sorry. The experiment you are referring to is now the tree test?

Mr. PACKARD. On the trees, yes.

Dr. BEDBROOK. Yes; in order to establish whether or not certain altered bacteria that we had that I described earlier were pathogens for those trees.

Mr. PACKARD. To your knowledge, were you the only company or the first company to perform those kinds of specific experiments? Are there other companies in the United States or around the world that are doing similar ones?

Dr. BEDBROOK. I do not believe there are other companies. As I understand it—I know for a fact—that there are university researchers carrying out similar experiments with similar strains.

Mr. PACKARD. And have you been in touch—have you coordinated your experimental work with those that are being done at the universities?

Dr. BEDBROOK. We have certainly cooperated. Well, we have conferred with those people. To say that it was a coordinated collaboration would be overstating it, but we have certainly conferred with them frequently on these organisms because they, too, are experts.

Mr. PACKARD. In your conferring, do you find that you are conducting the experiments basically with the same methodology that they are?

Dr. BEDBROOK. Yes, sir; with respect to the methodology of all of the experiments. This was done with not only consultation of the literature but also with leading pathologists in the area.

Mr. PACKARD. Did your scientists or your board members discuss at any time whether you would notify EPA or not before the experiments began?

Dr. BEDBROOK. The management group controlling this particular set of experiments included the officer or manager of regulatory affairs, and he distributed to all of the people involved in that management team the interim guidelines at some time soon after they were made available. Adherence to those guidelines was implicit in that management group. However, the two researchers which I have referred to earlier discussed and deliberated on the issue of whether or not they should conduct this experiment in the manner that they did, and they came to the conclusion that they should proceed.

So, they did that knowledgeable of the guidelines, having read the guidelines, and decided to proceed with the tests.

Mr. PACKARD. So, it was not an oversight; it was deliberated upon, and discussed, and determination was made that it was not necessary to inform or notify EPA.

Dr. BEDBROOK. Yes; because what these researchers' feelings about these organisms were was that—about the experiment, I mean—was that this did not constitute a release and that good microbiological practice as well as the tree itself would constitute a level of containment which could not be classified as a deliberate release, yes.

Mr. PACKARD. Is any of the information that you were seeking or the data, the conclusions of your experiment, were they considered by the company protected information, information that later you may want to patent, and was there concern that the information would be disseminated to the point where there would be a loss of some of the financial potentials later on for the company?

Dr. BEDBROOK. To my knowledge, there was no—you know, frequently in scientific circles we like to keep these things secret just so our competitors don't know about it, not in a business sense but in a scientific sense. There was no such intention or no such requirement for that under these circumstances nor was there from a proprietary standpoint.

The knowledge relating to pathogenicity by these bacteria, of these bacteria, about pathogenicity of these bacteria is not something we would attempt to keep in the private domain. Indeed, our senior pathologist reported to the American Plant Pathological Society and other meetings the results of these tests.

I might say at this point that there were no questions from those bodies as to the methodology of the tests.

Mr. PACKARD. Why did your company feel that it was necessary to conduct the experiments outdoors? Was there any specific reason why the decision was made to do it in the open on trees that were exposed?

Dr. BEDBROOK. I am glad you asked me that. The decision making process here was made in the light of an extensive program of pathogenicity testing in response to the EPA's request for that information. We wished to get that information to the EPA in time for a potential approval of an EUP by the spring of this year. Our program was ambitious. We wanted to furnish the EPA with as

much information with respect to the pathogenicity of this organism as we possibly could.

Given the various cultural constraints for different plant species at that time of the year, bearing in mind this was February—it was an exceptional February in California this year—but the trees which were dormant—and dormant trees are advised in the plant pathological literature as being ideal for this kind of test—could withstand much better the outdoor conditions than could, for cultural reasons, the plants such as the herbaceous plants in the greenhouse. So, that was one consideration.

The second consideration was one of space and the duration of the experiment in relationship to the trees. We have a limited amount of space in the greenhouse, and they felt that the tree experiment, for cultural reasons, that the trees would be healthy and OK outside, and in view of the large amount of physical space that they occupied in the greenhouse that that was the basis of the decision to do the experiment outdoors.

Mr. PACKARD. And the trees that you did the experimental work on were on the same rooftop as some of the greenhouses that are very nicely displayed in your report.

Dr. BEDBROOK. Yes; they were immediately adjacent.

Mr. PACKARD. Would the experiment, had it been done in one of your greenhouses on smaller trees or whatever, would it have produced different kinds of information than you were looking for on the trees out in the open?

Dr. BEDBROOK. The literature on this point really only says that one needs to use established trees and that are grafted rather than seedlings. I should specify with respect to physical constraints, I am really referring here to floor area, not upward height of the tree here.

Mr. PACKARD. In your experiment, injection was used. Is that a common way of exposing a plant to either bacteria or serum?

Dr. BEDBROOK. Right; as you can imagine, in nature, plants in general are not exposed to that kind of treatment. This would be what you might call a worst case type of scenario for the level, I mean the amount, of pathogen entering into plant tissue. It is a—and I have to repeat I am not a qualified plant pathologist—but my experts tell me that this is a common method and standardly adopted procedure for doing pathogenicity testing.

Mr. PACKARD. Normally, the injection would give you a worst case compared to the spraying which is probably the more normal procedure, certainly more duplicating of the natural environment?

Dr. BEDBROOK. For an example, yes.

Mr. PACKARD. The experiment was on how many trees again?

Dr. BEDBROOK. The total number of trees was approximately 50. I am sorry I don't have the——

Mr. PACKARD. And how many of those developed cankers?

Dr. BEDBROOK. The only trees that developed cankers in relationship to injection were those injected with the known pathogens.

I have to clarify this. There are several different things being injected. There are several different species of trees, and there are several different replicates of each species. I apologize for not having the absolute details of that here, but they can certainly be made available to you.

Mr. PACKARD. I think that my chairman has asked several questions on the cankers that I was interested in, but I won't pursue that any further. I think we understand that cankers did not develop on any of the injected trees except with known pathogens.

Dr. BEDBROOK. That is correct.

Mr. PACKARD. OK.

Dr. BEDBROOK. I have to say again that when I mean a canker, I mean a canker in terms of what an experienced plant pathologist observes and considers to be a canker, a pathogenic response.

Mr. PACKARD. Has AGS ever conducted similar tests to the one on the trees before where they injected genetically engineered organisms into a plant?

Dr. BEDBROOK. Prior to the work with *Pseudomonas syringae* and *Pseudomonas fluorescens,* AGS had not conducted pathogenicity tests. If you are asking me had experiments using injection methods for creating a worst-case scenario for disease on a plant species had been done prior to the tree experiment, then the answer is yes.

Mr. PACKARD. Of course. I am talking now about injecting genetically engineered organisms into plants on an experimental basis.

Dr. BEDBROOK. Prior to which time exactly?

Mr. PACKARD. Prior to the rooftop experiments.

Dr. BEDBROOK. Yes; in relationship to pathogenicity testing, there had been injection of these organisms. I am not sure I exactly——

Mr. PACKARD. I guess what I am asking——

Dr. BEDBROOK. The initial—sorry.

Mr. PACKARD. Is this the first and only time that such an experiment took place?

Dr. BEDBROOK. On the roof?

Mr. PACKARD. Yes.

Dr. BEDBROOK. Yes, sir. I am sorry. I misunderstood your question.

Mr. PACKARD. I am concerned a little bit, not from your point of view, but from a general regulation point of view, about greenhouses versus trees being a contained environment, along with others. You have, again, in your report, greenhouses that appear to be typical of most greenhouses that would be used for experimental purposes. Are they, in your judgment, a contained environment? What do you understand to mean by EPA's guidelines on a contained environment?

Dr. BEDBROOK. With respect to the question of do I consider the greenhouses to be a contained environment, there are various forms of containment and there are various levels of containment that we are familiar with. Greenhouses offer some form of containment by virtue—of course, "greenhouse" again is another fairly general term. I believe that our greenhouses at the company provide a level of containment, yes.

Does that answer the question?

Mr. PACKARD. Do you consider a greenhouse more contained than the trees that you worked on?

Dr. BEDBROOK. In the plant pathologists' view that were carrying out the experiment, the experiments conducted on the rooftop presented no greater chance of an environmental release than the experiments conducted in the greenhouse. That is not to say that the rooftop is as adequately a contained facility as the greenhouse. It

simply is to assure you that the procedural aspects of the experiment were part and parcel of the containment that they were perceiving.

Clearly, a rooftop—I mean, if it is raining, then the greenhouse is going to protect you from that and the rooftop is not.

Mr. PACKARD. But insects and air and water can transfer bacteria as easily as in an open environment?

Dr. BEDBROOK. That is correct, and we have some documentation as to the level of movement of bacteria by insects.

Mr. PACKARD. Let me get now to what I consider the fundamental purpose of this hearing rather than to perhaps get into some of the details that we have spent thus far in.

When did you come to AGS?

Dr. BEDBROOK. I was first an employee of AGS in the middle of 1982. Prior to that time, I had served on their scientific advisory board since 1980.

Mr. PACKARD. So, you were at AGS during all of this?

Dr. BEDBROOK. I was at AGS during the beginning of this laboratory work and present there during the course of the experiments under discussion.

Mr. PACKARD. I was under the impression that you had come after this particular rooftop incident, but apparently that is not true.

Dr. BEDBROOK. I think that maybe refers to our chief executive who came in June of last year.

Mr. PACKARD. I think you are correct. Mr. Buchart?

Dr. BEDBROOK. Mr. Buchart, that is correct.

Mr. PACKARD. I think you are right.

EPA's interim guidelines were issued October 17, 1984. I believe that AGS was quoted as saying that the company will proceed to test outdoors, in the outdoor laboratory, grown bacteria, until questions about regulating genetic engineering are resolved. Could you explain what needed to be resolved before you would comply with the interim requirements or interim guidelines?

Dr. BEDBROOK. I am not sure of the time of that particular quote. There were—we, of course, have been involved in attempting to get permission to do these tests over a prolonged period of time.

Mr. PACKARD. The quote is dated November 9, 1984 which was a little less than a month after the guidelines were issued.

Dr. BEDBROOK. I can't say exactly what that statement meant. It may have referred to whether or not we would require an EUP. The point is here that this was a rather unique—I would consider it to be a rather unique application to the EPA insofar as there was a vast body of evidence already pertaining to the fact that these organisms presented little or no risk. The NIH-RAC committee, as I mentioned, had already approved or recommended approval of the release experiment.

So, when we notified the EPA, we were not certain as to whether or not they would require us to apply for an EUP or not. So it could be that those comments were referring to that state of uncertainty in our minds.

Mr. PACKARD. Do you believe that the guidelines are clear enough that there should be no misunderstanding as to the procedures that a company should follow?

Dr. BEDBROOK. As I said in my statement, I feel that this controversy and this misinterpretation of guidelines that we have made is not as a function of any inadequacy of the guidelines themselves. I should say these are an interim policy, and there may be areas of refinement in the future, but I feel they are an adequate set of guidelines and I think they are an appropriate set of guidelines.

Mr. PACKARD. What did NIH approve for your testing purposes and what did you test?

Dr. BEDBROOK. The NIH-RAC committee approved the field testing of the deletion mutants of *Pseudomonas syringae.* We did no testing because, by the time we had RAC approval and we were waiting for the approval of the director of NIH, at that time, the EPA came in—and I assure you we were very pleased to hear that—and decided that they would be regulating this work under FIFRA.

Mr. PACKARD. And the second part of the question, what did you test?

Dr. BEDBROOK. In relationship to the NIH?

Mr. PACKARD. Yes.

Dr. BEDBROOK. We made no—the application was for a field test, Mr. Packard, and we made no such test because we never——

Mr. PACKARD. On the rooftop tests, I mean. You tested two types of bacteria, I believe, did you not?

Dr. BEDBROOK. That is correct, *Pseudomonas syringae, Pseudomonas fluorescens,* and *Pseudomonas pathovar syringae* which were the positive controls, plus the strains from which the *Pseudomonas syringae* and *Pseudomonas fluorescens* were derived.

Mr. PACKARD. Were these different bacteria than what NIH approved before?

Dr. BEDBROOK. The organisms were the same ones as the NIH approval.

Mr. PACKARD. One last question, Mr. Chairman, I think for the time being at least.

What recommendations would you make in terms of either rewriting the interim regulations or making additional regulations or removing some of the regulations? What recommendations would you make to prevent these kinds of incidents repeating themselves?

Dr. BEDBROOK. With respect to the guidelines themselves with relationship to the conducting of experiments, as I said, I feel they are adequate. I think that taking from the NIH guidelines the implementation of procedures of evaluation could be valuable. That is to say, organizations should establish committees in relationship to the EPA guidelines. I feel sure that the EPA will consider this kind of thing when they publish their full documents.

My feeling here is that there has been a genuine misunderstanding carried out by the plant pathologists within this organization as a consequence of their intimate familiarity with these organisms that they have been working with for a prolonged period of time. Bear in mind that these were organisms which the only scientific body and regulatory agency had said were exempt from any special forms of physical containment.

So, I believe this was a very special case. However, it is my view with hindsight, that this experiment would not have gone ahead under these circumstances in AGS if at that time we had had a

committee formed in relationship to the EPA regulations. So, I would say one addition that I would think would be appropriate to the guidelines would be proposals to design a committee within the organization making the application to approve all the experiments pertaining to the application.

Mr. PACKARD. Had you notified EPA, do you believe that would have delayed or altered your course of events?

Dr. BEDBROOK. Of course, that would be guessing, but from what I have seen in the newspaper, it seems to me it is quite possible, quite likely that the EPA would not have required any changes in our procedures.

Mr. PACKARD. The newspapers, the environmental community, and others have shown great concern about this incident. In your professional judgment, do you believe there is any cause for alarm in terms of dangers of altered organisms, microbes, escaping into the environment in your experimental process? Do you see any potential danger to human health or safety?

Dr. BEDBROOK. In my considered opinion, there is no possibility of danger to human health as a consequence of these experiments.

Mr. PACKARD. Thank you, Mr. Chairman.

Mr. VOLKMER. Thank you very much.

I still have a few more questions.

In reviewing this synopsis of the information we were provided, I would like to know if you had a Dr. Julianne Lindemann?

Dr. BEDBROOK. Lindemann, yes.

Mr. VOLKMER. Is she the immediate supervisor or is she the supervisor of the supervisor?

Dr. BEDBROOK. She is the immediate supervisor.

Mr. VOLKMER. And you also had Dr. Trevor Suslow?

Dr. BEDBROOK. That is correct.

Mr. VOLKMER. Is he the person in charge?

Dr. BEDBROOK. This set of experiments is conducted in our product research group, and Dr. Suslow who is a plant pathologist working with *Pseudomonas* organisms is the director of that group, and Julie is a senior pathologist in that group.

Mr. VOLKMER. And go back over just to make sure that I heard you right, there is only one technician who worked on these rooftop experiments on the trees during the whole period of the experiment. Is that correct?

Dr. BEDBROOK. To my knowledge, that is correct, yes, sir.

Mr. VOLKMER. So, there would be only one, two, or three sets of notes.

Dr. BEDBROOK. With respect to the observations made—I have checked into this specifically. With respect to the observations made on a regular basis, they were made by the technician. The observations were also made on a frequent basis by the senior pathologist that I mentioned.

Mr. VOLKMER. Now, specifically, it says in here that injection sites for RGP36 which was the ice nucleation negative, the *Pseudomonas syringae,* that you were experimenting with on an Alberta peach was slow to heal. That is down in the last paragraph, first sentence. Then it says there was also a previously unnoticed small canker near the areas injected on one Bing cherry tree.

Dr. BEDBROOK. Are you asking for my comment on these?

Mr. VOLKMER. Yes.

Dr. BEDBROOK. Sir, I have no specific comments about these notes since I know nothing about their——

Mr. VOLKMER. You don't know anything about their veracity or accuracy or anything? Is that what you mean?

Dr. BEDBROOK. No, I don't know. I mean, what I would be very happy to do would be to confer with Julie and Trevor as to the accuracy of these statements, but I am not——

Mr. VOLKMER. There is another statement in here. It says that:

A labeled branch injected with MS1650 was neatly pruned off one of the Alberta peach tress. This occurred after I noted the obvious flow of sap from one of seven injection sites on this branch.

You see, some of these things concern us.

Dr. BEDBROOK. Yes, sir, it seems to me, clearly, just glancing over this that the level of detail here means it is very probable——

Mr. VOLKMER. Somebody knows what is going on.

Dr. BEDBROOK. The person who wrote these must have had a very close association with the experiment. Since we are aware of the fact that the technician involved in these experiments was fired with cause and, at the time, indicated that he was going to take copies of his documentation of his experiments, then I think it is quite probable that that is the source of this information.

Mr. VOLKMER. Does that mean that you don't feel this is accurate, these statements?

Dr. BEDBROOK. This is not prepared by me, so I cannot comment on its accuracy.

Mr. VOLKMER. All right.

Dr. BEDBROOK. Let me say here that the one thing I will say is that, as I have said previously, I have no question in my mind about the validity of the results reported to the Environmental Protection Agency in relationship to these tests. There may be details here which need consideration by qualified pathologists, but the bottom line remains true, as far as I am concerned, which is relating to any questions of the validity of the results of the tests. I have no questions about those in my position as——

Mr. VOLKMER. Well, you can only go on what Dr. Lindemann told you that there were really no cankers that were showing soft tissue and so forth.

Dr. BEDBROOK. Both Dr. Lindemann and Dr. Suslow.

Mr. VOLKMER. And that is what you are going on.

Dr. BEDBROOK. It is the basis of these experienced pathologists that I would listen to, yes, sir, and believe them. These are colleagues of mine that I have worked with for a period of years, and I trust their opinions and have never had any reason not to.

Mr. VOLKMER. What has been their experience in conducting pathogenicity tests on deciduous trees?

Dr. BEDBROOK. Both of these people have had vast experience with *Pseudomonas* pathogens in the order of greater than 20 years collectively. Details of their experience with tree infections I am not aware of.

I went over this point with them, Mr. Chairman, in relationship to how one decides whether or not a pathogen or a reputed pathogen is in fact a pathogen. They said to me that they do it in several

ways. One is based on their experience, based on the literature, based on conferring with other colleagues in the area that they respect and know, and by presenting their information to forums such as scientific meetings.

In these particular tests, all of those forums, if you like, were used for the data evaluation.

Mr. VOLKMER. Then we have here information to the effect we have been furnished that there were cankers observed on the trees to which ice nucleation negative types of bacteria were injected. We have also been told that, you say, there were no observational cankers. We do know that they didn't conduct tests on the cankers if there were any. But you are saying actually there were no cankers. Is that correct?

Dr. BEDBROOK. In the opinions of my senior pathologists, as I mentioned before, there were no cankers that developed on the trees injected with the unaltered and the altered *Pseudomonas syringae* and *Pseudomonas fluorescens* in question.

Since I am starting to understand what may be the source of this concern here, in order to classify something as a canker, a canker is a description of a symptom, obviously. In order to say that a symptom is relating to a disease, you require experience.

Let me give you an example that comes from my personal experience recently. My youngest daughter is about 9 months old, and her day care group had a bout of chicken pox. Now, she is the third child that I have had, and I feel like I am a relatively good technician when it comes to dealing with children. When she developed a rash on her bottom, I immediately assumed that it was chicken pox by virtue of the fact that in her child care group there was an epidemic of chicken pox.

We took her to her doctor the next day. He took off her diaper and we said is that chicken pox and he said no, it is not chicken pox; it is a rash. If she had chicken pox, she would have a runny nose and a temperature and so on and so forth.

What I am trying to say here is that in the lack of experience, it is possible to make an observation, and you can be a competent technician, make an observation but just be plain wrong. All you have to do is have an expert or person experienced in this area to confirm that an observation that you think might be a particular disease is indeed a particular disease.

So, what I am saying, and I will reiterate this again, no cankers indicative of infection by *Pseudomonas* species were observed on any plant species, including the trees that were injected with the modified organisms. Neither were such observations made on the plant species with the unaltered bacteria. They were only observed in the opinions of our senior pathologists in the instances where known pathovars or known pathogens were injected.

I trust these results. I know these people. They are experienced, cautious, responsible individuals, and I am convinced that their opinions are valid and that the data that was submitted in request of an EUP supports all of the information that is presented in that application.

Mr. VOLKMER. I appreciate your testimony here today, Doctor. I have no other alternative, in my opinion, than to submit this information to EPA and to have them evaluate it as they are evaluating

the data that you presently have and take it along with that. We will continue, of course, to monitor the EPA in this regard. If we are not satisfied, we will probably have to call them back after today, but I hope this whole thing ends up satisfactorily.

I do believe that basically what I see is that at least AGS placed themselves—substituted your determination as to what qualified as far as the rooftop tests for the interim testing for EPA's decision-making, and I don't think that was wise. Do you agree on that?

Dr. BEDBROOK. I agree that there was a real lack of wisdom associated with that decision, yes.

Mr. VOLKMER. With that, unless the gentleman from California has anything further, we will proceed to the next witness. Thank you very much, Dr. Bedbrook. That will be your testimony for today. I appreciate it.

Dr. BEDBROOK. Thank you, Mr. Chairman.

Mr. VOLKMER. We will now have Mr. Steven Schatzow of the EPA.

Mr. Schatzow, your statement will be made a part of the record. I understand we have a fact sheet on this. Before we begin, please raise your right hand. Do you swear to tell the truth, the whole truth, and nothing but the truth, so help you God?

Mr. SCHATZOW. I do.

Mr. VOLKMER. Thank you. You may proceed.

STATEMENT OF STEVEN SCHATZOW, DIRECTOR, OFFICE OF PESTICIDE PROGRAMS, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. SCHATZOW. Thank you, Mr. Chairman and Congressman Packard.

We have prepared a fact sheet which tries to go through some of the background in terms of the issuance of this permit and which tries to put it in context. It also talks about the specific issues, both in terms of site selection as well as our investigation which we have been discussing today. I am going to try to summarize from this fact sheet to try to keep my remarks within the 10 minutes that you requested.

I will talk a little bit first about the background of FIFRA itself, the Act. It provides that before any pesticide can be distributed or sold, it must be registered through section 3 of the Act. There are specific guidelines in our regulations as to what kind of data is necessary under section 3 for registration. Those data do address microbial pesticides including both natural microbials and genetically altered or engineered microbials.

In addition under FIFRA, section 5 authorizes EPA to grant experimental use permits for limited use to enable prospective registrants to gather information about unregistered pesticides, to develop that kind of information so that a decision may be made about registration.

Once again, the kinds of data requirements for chemicals and for biologicals, including genetically altered biologicals, are contained within our regulations, and the regulations, at the same time, give us the flexibility to require additional information when necessary.

The regulations which implement the experimental use permit provide that it is generally presumed that an experimental use permit will not be required for small scale field testing, for testing of less than 10 acres terrestrial and less than 1 acre aquatic.

In October 1984, as has been discussed previously here, because of some concerns about even small scale testing of genetically altered and nonindigenous microbial pesticides, EPA put out an interim policy which required anyone who wanted to release such a pesticide into the environment to notify the Agency at least 90 days prior to the testing. The interim policy specified the kind of information and the data that was necessary to be submitted to the Agency and said that EPA would review that data within 90 days to determine whether an EUP would be necessary.

That interim policy very explicitly said that it did not apply to studies conducted in contained laboratories, growth chambers, greenhouses, or other contained facilities where there would be no direct release.

The AGS product fell within this interim policy. It was a genetically altered microbial with pesticidal properties. AGS submitted the notification in response to our interim policy.

It has been discussed briefly—I think it is gone into in more detail here—the kind of scientific process which we utilized to review the AGS notification. We had an internal review team within EPA both within my office, the Office of Pesticide Programs, and the other parts of EPA. We also asked for and got participation from both USDA and NIH, and we set up an independent subpanel of our Scientific Advisory Panel, six experts from around the country who are otherwise unaffiliated with EPA, and we asked them to review our scientific assessment on this notification. In fact, one of those experts, Dr. Colwell, will be testifying later.

That subpanel provided, first, individual written comments and then convened in an all-day meeting to review the experiment and to formulate recommendations.

Both the agency scientists as well as the independent subpanel as well as the experts from other Federal agencies agreed that the experiment posed very little likelihood of risk, but they also agreed that it would be appropriate to require further information to be able to document the low likelihood of risk in terms of some of the issues involving survival characteristics, the identity of the microorganisms, colonization, competitiveness, pathogenicity to plants, and monitoring and detection methods.

So, we informed AGS in February 1985 that an EUP would be required, and we told AGS what kind of additional data would be necessary.

AGS then submitted an EUP application addressing our requests in June 1985, and we went through a review process that was very similar to the one we had gone through in terms of the notification. Some major differences or additions were that we had an explicit interagency peer review panel from USDA, NIH, and FDA and that in addition to going back to our SAP subpanel, we also went to the public and put out public notice that we had received the application, notice of the availability of the data, and an opportunity for the public to comment.

We received two public comments, one of which did raise some substantive concerns. We carefully reviewed those scientific concerns raised and, in fact, went back to the experts cited by the commenter to get their opinion of the views cited.

The major issues that were addressed include those in terms of our scientific assessment that are mentioned on page 4 of our fact sheet. We went through extensively the issue in terms of rainfall patterns, for instance, and concluded, finally, in November 1985, that the proposed experiment did not present foreseeable risks either to human health or the environment, and we issued the two EUP's to AGS on November 14, 1985.

The risk assessment did not focus very specifically on the specific site details because our conclusion, based on the data before us, is that there was not significant risk in terms of the experiment either at the site or around the site. We did require in the EUP's that AGS must notify EPA 15 days before it started the experiment. In addition to that, we required in the EUP that there must be an authorized representative of EPA present when the experiment is carried out.

The EUP's, in addition, provided for monitoring during the experiment, aerial monitoring to be undertaken by EPA and AGS together. Therefore, it necessitated a site visit by EPA before the testing could take place, and there were mechanisms in place for EPA to inspect the site prior to the experiment and to amend the EUP's as appropriate based on a site visit.

EPA personnel visited the site in December 1985 and determined, based on the specific site characteristics, that AGS would have to gain access to adjacent property in order to conduct the monitoring specified in the EUP's and, therefore, EPA amended the terms of the EUP's on January 3, 1986 to require that written permission be obtained from the contiguous land owners on the west and the south sides of the test plot in order to enter their property for purposes of inspecting, sampling of vegetation, and for the possibility of treating with microbiocides.

We also required that all contiguous land owners had to be advised of the proposed experiment in writing at least 15 days prior to initiation of the experiment.

In terms of the final issue that you have been discussing today, the Agency was first notified of the allegations concerning the AGS experiments in terms of the rooftop experiments on Monday afternoon, February 24. We did a very preliminary assessment. We were informed by AGS that the trees were injected in an open environment.

Based on this apparent violation of our interim policy, we opened a full investigation of all allegations on Thursday, February 27. That investigation has two major elements. One is a complete audit of all the AGS records and the facilities to assure the credibility of the data that had been submitted to us and that we reviewed, and, second of all, to review the circumstances surrounding the AGS application to determine whether there were violations of Federal laws, policies, and procedures and, if so, what appropriate response should be taken.

The investigators arrived at the AGS facility on Friday afternoon, February 28. The investigation is scheduled to be completed by March 24.

I would note in closing that the Agency has no evidence at this time to suggest that the AGS data are invalid or at this time to call into question the Agency's finding that the limited field test would not result in any foreseeable risk to human health or the environment.

Thank you, Mr. Chairman. I would be pleased to answer questions.

[The prepared statement of Mr. Schatzow follows:]

EPA FACT SHEET

I FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

(1) Overall Scope and Authority

* Risk/benefit balancing statute -- requires pesticide to perform its intended function without causing unreasonable adverse effects on people or the environment

* Defines "pesticide" as any substance intended for preventing, destroying, repelling, or mitigating any pest

* FIFRA § 3 requires registration of all pesticides distributed or sold in commerce

  - applies to all chemical and microbial pesticides, including genetically engineered microbial pesticides; other biological products exempt under FIFRA § 25
  - requirements at 40 CFR 162

* Pesticide registration must be supported by adequate data

  - data requirements at 40 CFR 158 give flexibility to require whatever data necessary to assess risks
  - 40 CFR 158.65 emphasizes case-by-case analysis of genetically engineered microbial pesticides
  - 40 CFR 158.45 allows for waivers of data requirements where appropriate depending upon specific microorganism, how it has been engineered, and specific use pattern
  - guidance for studies required by Part 158 published in Pesticide Assessment Guidelines for microbial pesticides (Subdivision M)

* FIFRA § 5 authorizes EPA to grant experimental use permit (EUP) for limited use of unregistered pesticide to develop data necessary for registration

  - procedural requirements at 40 CFR 172
  - data requirements at 40 CFR 158 -- case-by-case analysis for genetically engineered microbial pesticides; additional data or waivers where appropriate
  - 40 CFR 172.3 requires EUPs for all tests on greater than 10 acres of land or 1 surface acre of water
  - generally presumed that EUP not required for smaller testing -- at time regulation issued (1975), risks from such tests considered sufficiently small as not to warrant EPA oversight
  - presumption not applicable to certain microbial pesticides covered by Interim Policy

(2) Interim Policy on Small Scale Field Testing (Interim Policy)

* Issued on October 17, 1984 (49 FR 40659) to address special concerns raised by even small scale use of genetically altered and non-indigenous microbial pesticides

  - ability to survive and replicate
  - potential for genetic transfer
  - ability to spread independently from test site
  - potential lack of natural control mechanisms

* Does not apply to studies conducted in contained laboratory, growth chamber, greenhouse, or other contained facilities where there is no direct release of the microbial pesticide into the environment

* Requires notification to the Agency at least 90 days prior to the testing. Interim Policy specifies information and data to be submitted to Agency, namely

  - detailed information on the test and the microbe to be tested, including identity, natural habitat, host range, growth and survival, effects on non-target organisms, and for genetically engineered microbes, information on construction, potential for genetic transfer, and competitiveness

* EPA has up to 90 days to review a notification and determine whether an EUP is required

  - if all necessary questions are addressed and no significant risk is foreseen, then an EUP is not necessary and the test may proceed. If questions remain and the Agency needs additional data or wants to ensure EPA oversight, then an EUP may be required.

* EPA intends to amend EUP regulations to embody provisions of Interim Policy

(3) Applicability of Interim Policy to AGS Test

* AGS product - non-ice nucleating bacteria (INA^-) - and experiment are subject to Interim Policy

  - INA^- bacteria are pesticides -- INA^- applied with intent to control pest microorganisms, i.e., INA^+ bacteria; chemicals are also registered for control of INA^+ bacteria in order to reduce frost damage
  - INA^- are genetically engineered -- recombinant DNA techniques are used to construct INA^- bacteria
  - proposed AGS experiment involves direct release of genetically engineered bacteria into environment

II. REVIEW PROCESS FOR AGS EXPERIMENT

NOTIFICATION

(1) AGS submitted notification (October 1984) in response to EPA's Interim Policy

(2) OPP scientific staff evaluated EUP application and developed scientific assessment

* review team consisted of six Ph.D. scientists - including microbiologist, microbial ecologist, plant pathologist, and toxicologist

(3) OPP scientific assessment was peer reviewed -

* by other EPA scientists outside OPP

* by an independent panel of experts assembled as subpanel of the FIFRA Scientific Advisory Panel (SAP). Subpanel members are academics picked for their specific expertise as related to the AGS experiment:

- Dr. Wendell Kilgore, Chairman (Microbiologist)
- Dr. Martin Alexander (Soil Microbiologist)
- Dr. Randolph Borys (Meteorologist)
- Dr. Robert Colwell (Community Ecologist)
- Dr. Susan Hirano (Plant Pathologist)
- Dr. James Tiedje (Microbial Ecologist)

* Subpanel provided individual written comments and convened an all day meeting to review the experiment and formulate recommendations. USDA and NIH participated in subpanel meeting.

(4) Conclusions: Agency scientists and subpanel agreed that experiment posed very low likelihood of risk. Low risk nature of proposed experiment needed to be substantiated with additional scientific data and further documentation of existing data on identity, survival characteristics, colonization, competitiveness, pathogenicity to plants, and monitoring/detection methods.

(5) AGS informed that EUP required (February 1, 1985)

* EPA required AGS to provide additional data/documentation.

EUP APPLICATION

(1) AGS submitted EUP application addressing EPA requests (June 27, 1985)

(2) Review process was similar to that for notification (attachment 1) -

* OPP scientists review and develop scientific assessments

* Intra-Agency Peer Review

* Inter-Agency Peer Review (USDA, NIH, FDA)

* SAP Subpanel Peer Review

(3) OPP published notice of receipt of EUP application in FEDERAL REGISTER and solicited public comment - Non CBI portion of application (i.e., virtually all) made available to public

(4) EPA received two public comments; only one raised substantive concerns

* EPA carefully reviewed comments in consultation with subpanel and other independent scientists, including those experts cited by commenter (Drs. Odum, Schnell)

* EPA prepared response to comments (available to public)

(5) Scientific Assessment --

* Major scientific issues addressed were -

- plant pathogenicity
- potential effects on survival and geographic range of plants and insects
- potential effects on rainfall patterns

* Assessment of issues was thorough and involved extensive peer review -- as example:

- meteorologist placed on SAP subpanel due to rainfall concerns raised in earlier NIH review
- potential effects on rainfall discussed at SAP subpanel meeting on AGS notification
- EPA contacted experts cited in public comments and again consulted SAP subpanel members
- all atmospheric scientists consulted by EPA agreed:

* no firm evidence that INA^+ bacteria play role in precipitation formation
* virtually no likelihood that displacement of INA^+ by INA^- bacteria on plants in test plot would affect precipitation patterns

(6) Conclusion - EPA concluded that the proposed experiment posed no foreseeable risk to human health or the environment (Attachment 2). On November 14, 1985 EPA granted AGS two EUPs (one EUP for Pseudomonas syringae and one EUP for Pseudomonas fluorescens).

III. TEST SITE LOCATION

(1) EPA grants two EUPs to AGS (November 14, 1985)

* Risk assessment does not focus on specific site details because EPA believes conclusion of low risk is valid, irrespective of specific site (attachment 3)

* EUPs require AGS to notify EPA 15 days before starting experiment

* EUPs require authorized representative of EPA to be present when experiment is carried out

* EUPs provide for aerial monitoring during experiment

  - joint undertaking by EPA and AGS
  - necessitates site visit by EPA before test

* Mechanisms in place for EPA to inspect site prior to experiment and to amend EUPs, as appropriate, based on site visit

(2) EPA personnel visit test site (December 12, 1985)

* EPA determined that AGS would have to gain access to adjacent properties in order to conduct monitoring specified in EUPs

(3) EPA amends terms of EUPs (January 3, 1986)

* before initiating experiment, written permission must be obtained from the contiguous landowners on west and south sides of test plot to enter their property for purposes of inspection, sampling of vegetation, and/or treating with microbiocides

* all contiguous landowners on the west, south, and east sides of the test plot must be advised of the proposed experiment in writing at least 15 days prior to initiation

* OPP representative testifies before the Monterey County Board of Supervisors, responding to questions concerning EPA's evaluation of the site location (January 27, 1986)

IV. INVESTIGATION OF AGS

(1) Agency first notified of allegations concerning AGS experiments on Monday afternoon, February 24

(2) Agency makes preliminary assessment and is informed by AGS that trees were injected in open environment

(3) Based on apparent violation of Interim Policy, EPA opens full investigation of all allegations involving AGS on Thursday, February 27

* Investigation has two major elements:

- Audit of AGS records and facilities to assure credibility of data in AGS application
- Review of circumstances surrounding AGS application to determine any violations of federal laws, policies, or procedures

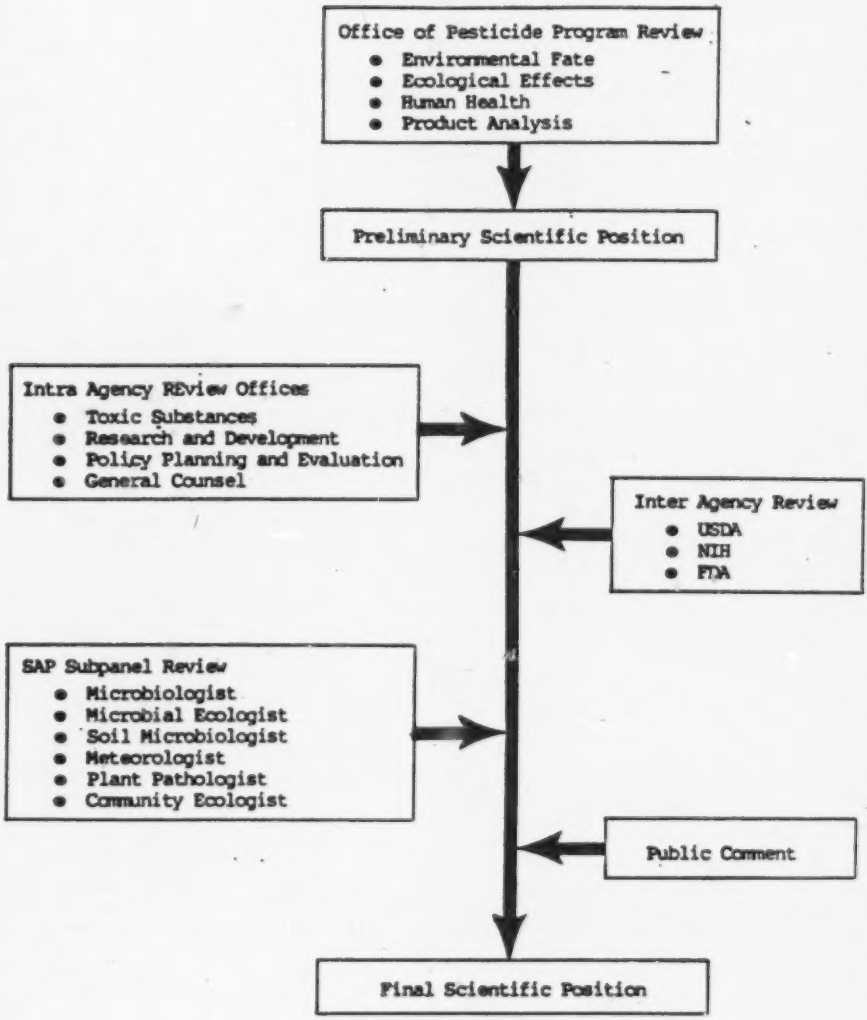
* Investigators arrive at AGS facility on Friday afternoon, February 28

* Investigation scheduled to be complete by March 24

(4) Agency has no evidence at this time to suggest that AGS data are invalid or to call into question Agency's finding that limited field test would not result in any foreseeable risk to human health or the environment

ATTACHMENT 1

EPA ASSESSMENT PROCESS FOR AGS APPLICATION



ATTACHMENT 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 14 1985

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Application of Advanced Genetic Sciences for Experimental Use Permits -- DECISION MEMORANDUM

FROM: Steven Schatzow
Director
Office of Pesticide Programs (TS-766C)

TO: John A. Moore
Assistant Administrator
for Pesticides and Toxic Substances (TS-788)

ISSUE

Should the Agency approve or deny the applications from Advanced Genetic Sciences for experimental use permits to conduct a small scale field test of two genetically altered strains of naturally occurring ice nucleating bacteria? If approved, under what conditions should the experiment be conducted?

DISCUSSION

Description of AGS Products

Pseudomonas syringae and Pseudomonas fluorescens are two naturally occurring bacteria which contribute to the ice nucleating process, i.e., they aid in the formation of frost on plants. Advanced Genetic Sciences, Inc. (AGS), 6701 San Pablo Avenue, Oakland, California 94608, has deleted the genetic material in P. syringae (Strain S203) and P. fluorescens (Strain MS1650) which codes for the production of a protein capable of causing ice

nucleation. These ice nucleating deletion mutants that are negative for ice nucleation (*P. syringae*, strain RGP36 N1 and *P. fluorescens*, strain GJP17B R2) are referred to in this memorandum as "INA- products," as opposed to the naturally occurring ice nucleating (INA^+) and non-ice nucleating (non-INA) bacteria. AGS is proposing to apply its INA^- products to strawberry plants within a small test plot in the central coast area of California in order to evaluate the potential of these products to control frost damage under actual field conditions. In the experiment, the INA^- products would be applied to the plants for the purpose of innoculating the emerging blossoms before naturally occurring ice nucleating bacteria (INA^+) become established, with the intent of inhibiting frost formation on the blossoms until the temperature drops to approximately -5° C (23° F). The experiment is scheduled to run a total of 42 days, with monitoring to follow for several months.

Summary of Agency Review of Applications

Pursuant to the Agency's Interim Policy on Small Scale Field Testing of Microbial Pesticides, AGS notified us of its intent to conduct field tests of its INA^- products. The AGS notification was received on November 5, 1984. Based on requests made by the Agency, additional information was received from AGS on January 10, 1985.

The information and data submitted by AGS in its notification were reviewed by the scientific staff of the Hazard Evaluation Division (HED) of the Office of Pesticide Programs (OPP), the Intra-Agency Work Group on Biotechnology, and a special subpanel of the FIFRA Scientific Advisory Panel (SAP). The Agency received

written comments from the individual members of the SAP subpanel in addition to the transcript of the January 22, 1985 meeting of the SAP subpanel and the consensus report of the SAP subpanel. Based on its review of the AGS submission and the comments and recommendations of the SAP subpanel, HED issued its scientific position on the AGS proposal by memorandum of January 30, 1985 (see Attachment 1).

By letter of February 1, 1985, the Agency advised AGS that an experimental use permit would be required prior to the release of the INA⁻ products into the environment (see Attachment 2). The letter requested additional information on a number of factors, including the test plots and testing conditions, survival and competitiveness of the INA⁻ products, preparation and identification of the INA⁻ products, and monitoring plans for detecting offsite dissemination of the INA⁻ products. The letter to AGS also made a number of recommendations concerning the conditions of the AGS proposal and the data needed to support applications for experimental use permits.

Applications for two experimental use permits, AGS 3001.1 (P. syringae, Strain RGP 36 N1) and AGS 3001.2 (P. fluorescens, Strain GJP17BR2), were received by the Agency from AGS on July 2, 1985. Following a preliminary review by HED, notice of receipt of the applications was published in the Federal Register on August 21, 1985 (50 FR 33841) (see Attachment 3). A 30-day comment period was provided.

Based on its review of the AGS applications in light of the original AGS notification, HED developed a preliminary scientific position in a memorandum dated August 27, 1985 (see Attachment 4). The memorandum addressed the scientific adequacy of the applications in meeting the requirements for an experimental use permit, including the specific requests for information set forth in the Agency's February 1, 1985 letter to AGS.

Copies of the AGS applications and HED's preliminary scientific position were provided to the following for review and comment: U.S. Department of Agriculture (USDA), National Institutes of Health (NIH), Food and Drug Administration (FDA), members of the SAP subpanel, and the Intra-Agency Work Group on Biotechnology.

In response to the Federal Register notice and distribution of relevant materials to the various agencies and individuals mentioned above, OPP received responses from the following:

1. General Public -- Mr. Edward Lee Rogers on behalf of the Foundation on Economic Trends, Jeremy Rifkin, et al.;
2. Other Federal Agencies -- FDA, USDA, NIH;
3. SAP Subpanel -- Drs. Kilgore, Alexander, Colwell, Hirano, Tiedje, and Borys;
4. Intra-Agency Work Group -- Office of Toxic Substances and Office of Research and Development.

The comments received address two major issues: (1) compliance with the data requirements expressed in 40 CFR Part 158 for an experimental use permit, and (2) the persistence, competitiveness,

and outward dissemination from the test plot of the INA⁻ products and the corresponding impact on patterns of precipitation. With the exception of Mr. Rogers, no commenter gave any indication that the applications should be denied. Based on our evaluation of these comments, in light of the supporting data, we have concluded that AGS has complied with the intent of 40 CFR Part 158, and that the supporting data are adequate to reach a regulatory decision regarding issuance of the experimental use permits and their subsequent impact on the environment (see Attachments 5 and 6). In the evaluation of the supporting data, sufficient studies are available to show that at low levels, the INA⁻ products should not overrun the naturally occurring epiphytic flora present outside the test site, but rather coexist with them. At these low levels, the INA⁻ products would not have any significant impact on the indigenous populations of bacteria that some have suggested may have an effect on precipitation patterns.

Our review of the applications, supporting data and comments received also indicates that approval of the AGS applications subject to appropriate conditions would provide the type of information needed for subsequent regulatory decision-making on these and other similar products. It also appears that, in the event the anticipated pesticidal properties of these products are borne out by the proposed field tests, the beneficial impact of these products (or some future variety of these products) for agricultural production could be significant. Moreover, when compared to chemical pesticides registered for the same purpose that act by nonselectively destroying the epiphytic

flora of the plant, the unique action of the INA⁻ product is likely to be less disruptive to the surrounding ecosystem.

In keeping with the intent of the experimental use permit program, the types of information the Agency required to support AGS's applications and that will be developed during the conduct of the field tests are also supportive of future product registration decisions. AGS has already done extensive testing of its INA⁻ products in greenhouse or other contained conditions. In order to test whether the INA⁻ products will have the desired properties under actual use conditions, limited field testing is necessary. Under the terms of the experimental use permits, the results of the tests must be reported to the Agency and sufficient oversight and monitoring of the tests must be provided. As always, the Agency reserves the right to revoke an experimental use permit, at any time, if its terms or conditions are being violated or are inadequate to avoid unreasonable adverse effects on the environment.

ALTERNATIVES

The Agency, in its deliberations, has evaluated the alternatives to permitting the INA⁻ experiments to go forward as proposed by AGS. Originally, OPP had the option of permitting the experiments to proceed without experimental use permits. This option was rejected by the Agency in its February 1, 1985 letter to AGS. Many of the modifications to AGS's original proposal, as reflected in its applications for experimental use permits, are a direct result of concerns raised by the Agency at that time.

In the notification submitted to the Agency on October 31, 1984, AGS stated its intent to conduct a maximum of seven test trials. Each test plot would consist of 0.38 acres which included a 0.1 acre planted zone surrounded by a 10 meter wide bare soil buffer zone. The test called for using 3×10^{12} cells suspended in a total volume of 3 liters per test site. AGS would monitor the populations of non-INA and INA^+ bacteria. Samples would be taken from the treated plants, control plants, and soil within the test plot, as well as at various distances from the test plot to assess drift and dissemination.

In response to Agency concerns, and to minimize exposure and the potential of any adverse impact on the environment, AGS further modified its proposal. The experimental program submitted by AGS outlined these conditions. The proposed test would involve a single test plot for both INA- products within a test site of 5 acres. A 0.2 acre treated area will be surrounded by a 15 meter wide, bare soil buffer zone in the center of a five acre parcel. A total of 2400 strawberry plants would be included in the test zone, and the test zone would be treated with 8×10^{12} cells in a total volume of 20.0 liters. A specific design for sampling (where samples will be taken, times of sampling, methods of sampling) of the treated plants, of insects in the test plot, of soil, and of neighboring untreated plants was delineated. Label changes which provide for applicators to wear full protective clothing and respirators during application and a 12 hour reentry interval after treatment have been made. A list of conditions included in the AGS applications follows:

1. Experiment would utilize a single test plot within a test site of 5 acres.
2. Treated area would involve 0.2 acre surrounded by a 15 meter wide, bare soil buffer zone in the center of a five acre parcel.
3. A total of 2400 strawberry plants would be included in the test zone.
4. The test zone would be treated with a total of 8×10^{12} (4×10^{12} of each strain) in a total volume of 20.0 liters of water.
5. Applicators would wear full protective clothing, including whole body water-proof spray suits, hats, gloves, boots, goggles and NIOSH-approved respirators during application
6. A 12 hour reentry interval would be observed before unprotected technicians go back into the treated area.
7. Treatments would be applied with low pressure hand-held sprayers with nozzles adjusted to produce large droplets which have rapid settling velocities.
8. Samples would be taken from within the treated area, the bare soil buffer zone, outside the buffer zone, and from gathered insects within the treated zone.
9. Leaves, blossoms, insects, and soil samples would be sealed in sterile plastic bags and stored in an ice chest during transport to the AGS laboratory.
10. Samples would be taken two weeks and one week prior to the

first spray application, the day of spray application, and at approximately 2, 5, 14, 21, 28, 35 and 42 days after the first spray application.

11. If the released strains are detected at any time on plants or soil from outside of the plot area, monitoring of soil and weeds outside of the plot would continue at monthly intervals for up to one year.

12. If the released strains are not detected on plants or soil from outside of the plot area, monitoring of soil and weeds outside of the plot would continue at monthly intervals for three months.

13. If the released strains are detected on foliage sampled in a 1.0 meter strip zone located outside the test plot adjacent to the buffer zone, then Kocide and streptomycin (antimicrobial pesticides) would be immediately applied in a 10 meter wide area.

14. After test is completed the plants in the test zone will be incinerated on site with a propane fueled torch. All plant debris remaining must be disked into the soil.

15. All materials used for isolation, transfer and propagation of mutant bacteria would be autoclaved prior to disposal.

16. During transportation between the Oakland laboratory and the field site, bacterial cultures and plant parts must be secured in sealed, leakproof containers.

17. After application, sprayers must be sanitized with 70% ethanol.

Based on its review of the AGS applications, supporting data, and comments received, the Agency must decide whether to (1) approve the applications as submitted, (2) deny the applications, or (3) approve the applications subject to additional restrictions.

RECOMMENDATION

Based on our review of the available data and information, it is recommended that the Agency approve the AGS experimental use permit applications subject to the following additional conditions and restrictions:

1. Notification as to the date of initiating the test must be received by the Office of Pesticide Programs at least 15 days prior to testing.
2. The test trial must be carried out when an authorized representative of EPA is present.
3. As an extension of environmental fate monitoring, air samples must be taken during the test trial to measure bacteria above the test plot.

__X__ I concur in this recommendation.

_____ I do not concur in this recommendation.

14 Nov 85
Date

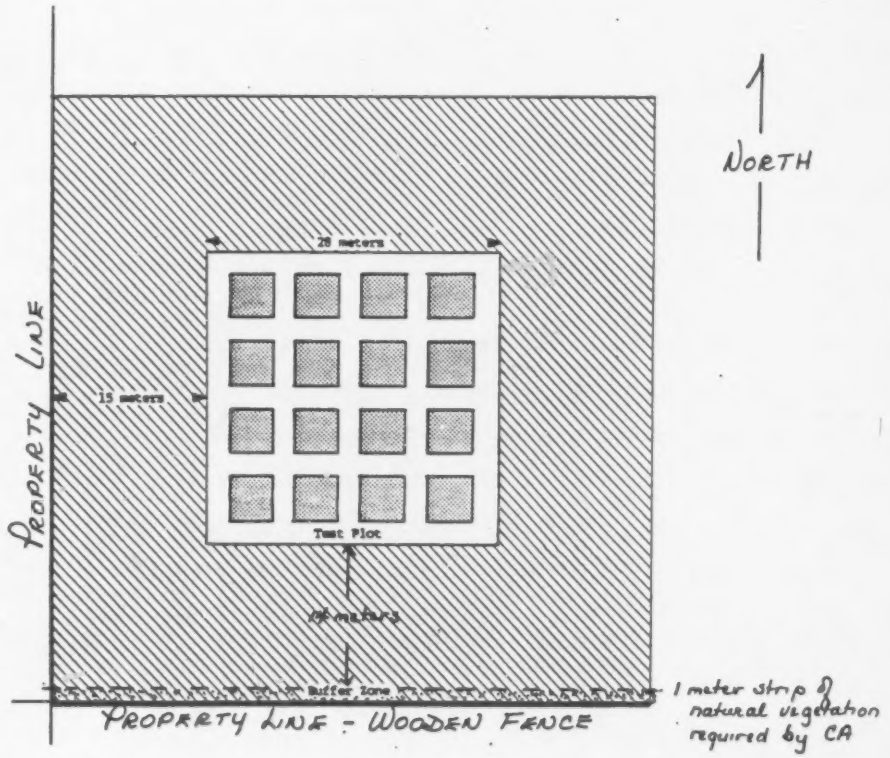
John A. Moore

ATTACHMENT 3

TEST PLOT AND SAMPLING

- Area to be treated — 0.2 acres
- 16 treatment blocks, 150 strawberry plants/block
- 2400 strawberry plants total
- Amount of material to be applied — 8×10^{12} viable cells (max.)
- Sampling — leaves, foliage, blossoms, insects, deposition of bacteria

  Samples to be taken inside and outside test plot



Steven Schatzow

In June 1984, Steven Schatzow became the Director for the Office of Pesticide Programs at the U.S. Environmental Protection Agency. Mr. Schatzow is responsible for managing and directing the pesticide activities of the Agency which include the development of strategic plans for controlling adverse effects of pesticides and for the establishment of policies and regulations which will lead to a more judicious and evironmentally acceptable use of pesticides.

His office has responsibility for the registration of all pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); establishing tolerance levels for pesticide residues occurring in food and feed; monitoring residue levels in food, man, fish, and wildlifes and their environments and reviewing environmental impact statements concerning pesticide use.

Prior to June 1984, Mr. Schatzow served as the Director of the Office of Water Regulations and Standards. He had the responsibility for the development of regulations and guidance for the control of industrial water pollution, for the development of water quality standards, for ambient water monitoring, and the Agency's Oceans program.

Mr. Schatzow joined the Environmental Protection Agency in 1976 as a staff attorney in the Office of General Counsel. He served from 1978 until 1980 as Deputy Associate General Counsel for Effluent Guidelines. He became Acting Director for the Office of Water Regulations and Standards in February 1980, and Director in June 1980.

Prior to joining EPA, Mr. Schatzow was a VISTA attorney, a consultant to the Canadian Government for urban affairs, and in private law practice in Washington.

Mr. Schatzow has a B.A. from Yale University, a J.D. from the University of Chicago and a Ll.M. in Urban Law from George Washington University.

Mr. VOLKMER. Thank you very much, Mr. Schatzow.

I would like to know, first, you said you were notified, I believe, February 24?

Mr. SCHATZOW. That is right.

Mr. VOLKMER. By whom were you notified?

Mr. SCHATZOW. I was notified by our press office which had received a telephone call, I understand, from The Washington Post.

Mr. VOLKMER. In other words, it wasn't from AGS that you were notified that the tests had been done in this method?

Mr. SCHATZOW. No. That is correct.

Mr. VOLKMER. It was basically from the media, then.

Mr. SCHATZOW. That is correct.

Mr. VOLKMER. You have also been furnished now a synopsis and we will actually furnish you with a copy of the letter that we have received alleging basically that there were cankers developed in some of the fruit trees on the branches of the *Pseudomonas syringae* and the *Pseudomonas fluorescens* that were actually the ice-minus negative types.

Does that raise any questions in your mind?

Mr. SCHATZOW. I think it would be completely premature for me to comment on that at all.

Mr. VOLKMER. I am just asking if it raised any questions.

Mr. SCHATZOW. Does it raise questions? To the extent that there are allegations that there are some canker type sores that relate directly not to the control but to the ice-minus, that would certainly raise some concerns, yes.

Mr. VOLKMER. I mean, that is something that would have to be looked into and investigated, would it not?

Mr. SCHATZOW. Yes, sir.

Mr. VOLKMER. I am not saying that it is necessarily true. I am just saying it is something that you have to look into.

Mr. SCHATZOW. I agree.

Mr. VOLKMER. I appreciate that, because we will probably have to ask you later, either formally or informally, the results of that.

Mr. SCHATZOW. Again, our investigation will be completed on March 24, and I assume we will be able to give a complete report on that issue at that time.

Mr. VOLKMER. I appreciate it.

Now, also, does the fact that the data submitted to EPA in support of the EUP was conducted in the rooftop experiment raise any questions or concerns?

Mr. SCHATZOW. Well, I think there are two types of questions. We are obviously very concerned about the fact that the experiment was conducted on the roof and not within the greenhouse. We believe that is a violation of our policy.

From a scientific point of view, it is unclear from the people that we have talked to thus far that in terms of the validity of the tests that they are affected negatively by testing on the roof. There are people, as I understand it, and this is pretty preliminary, who believe that in terms of the validity of that kind of a test, testing for the pathogenicity itself, that it is just as suitable to test on a rooftop as it is to test within a greenhouse.

Mr. VOLKMER. The question I have is a natural one, and I am sure your plant pathologists will review it, because I think they

would be the ones who would be more appropriate and not I, but the question I have is if it is necessary to test the reliability or whatever you have, how it actually operates, of the bacteria, in the greenhouse with a 20 plus or minus 5 °C and with certain moisture conditions, et cetera and yet you can do it on a rooftop when it is 60, 70, or 80 degrees and winds are blowing and it is dry.

Mr. SCHATZOW. We will certainly be interested——

Mr. VOLKMER. Does that raise any questions?

Mr. SCHATZOW. It may. Again, I have only had some preliminary discussions. This is very recent information that we have received. Again, there is a variety of testing that is done in a variety of different environments, and small scale field testing is often what is done to gather information. So, it is not that unusual.

Mr. VOLKMER. All right. Then I will get off of this. In my discussions, I have been told also that at certain points in a tree's growth during the year and due to certain temperatures, et cetera, it is more difficult for the pathogens to operate. In other words, they kind of go dormant at certain times. I don't know if that is correct or not, but somebody has told me that. That, I think, would have some effect on both the positive and the negative as to whether it did or not react.

However, what I am really concerned about is, do you feel—let me ask you this—that EPA has been misled by AGS in their application by not disclosing fully the fact that the tests were done on the rooftop?

Mr. SCHATZOW. I couldn't say until after the results of our investigation. The question, I think, that we are obviously going to have to look at is whether that altered environment does or does not affect the findings of the test and what is or is not the validity of the tests. That is going to take our investigation to do that.

Mr. VOLKMER. Well, as one who used to practice law, it always concerned me when somebody left something out or didn't quite tell the whole story. I always question what else was left out besides.

Mr. SCHATZOW. And that is why, Mr. Chairman, we are doing a full investigation of all the data to support this application, not merely the data from this rooftop test.

Mr. VOLKMER. Then, if the ice-minus bacteria did cause some cankers on these fruit trees, then you would have to reconsider the whole field test, would you not?

Mr. SCHATZOW. I think it is clear that if the ice-minus were determined to be a plant pathogen, contrary to all the other evidence we think we have seen, but if it were determined to be a plant pathogen, we sure would have some very serious reservations about allowing a field test of this, yes, Mr. Chairman.

Mr. VOLKMER. Do you have the authority to withdraw the EUP?

Mr. SCHATZOW. Yes, Mr. Chairman. We have the authority to withdraw it or to amend it as necessary. The EUP, although it is in force, cannot go into effect until the Agency is notified.

Mr. VOLKMER. I would appreciate it if during the investigation your staff out there examines all laboratory notes that are available.

Mr. SCHATZOW. I believe we will. I believe that is standard practice. Certainly, we will be examining the laboratory notes as they

relate to these allegations in terms of the outdoor test in great detail.

Mr. VOLKMER. If you do not object, I may request that my staff be permitted to examine those notes or at least copies of those notes.

Mr. SCHATZOW. I am checking with my counsel here in terms of the legal authority.

Mr. VOLKMER. We will take that up at a later time.

Mr. SCHATZOW. We can follow up on that, certainly. AGS may be willing to release those.

Mr. VOLKMER. Yes. There is a question of proprietary information and all that. I understand that.

On the test site, do you consider this a remote site?

Mr. SCHATZOW. No, I do not.

Mr. VOLKMER. But don't you require these to be held in remote sites?

Mr. SCHATZOW. No, we do not. Let me go over that if I can. First of all, to put this into context, the Agency receives applications for about 500 different experimental use permits every year. There is nothing in the Federal regulations which give us site control other than in terms of issues of health and safety. That is to say, we can require specific, or negate certain sites because they pose specific environmental risks, but there are no criteria in our regulations which, for instance, say that sites for experimental use permits must be "remote."

Our Science Advisory Panel, in reviewing the notification and our staff in looking at it suggested that, for a variety of reasons, it would be preferable to have a remote site, and the Agency did and does believe that it would be preferable to have a remote site.

Mr. VOLKMER. In other words, you would prefer that the site be other than where they have determined the site to be.

Mr. SCHATZOW. Yes. Again, let me make it clear I am not saying that the site is unacceptable from a health and safety point of view. I am saying that for a variety of reasons, some of which you have elucidated earlier, I don't think it is a great site.

Mr. VOLKMER. Not conducive to public perception of safety.

Mr. SCHATZOW. Certainly not.

Mr. VOLKMER. Did you all or did you not visit the site before approving it?

Mr. SCHATZOW. The site was not visited prior to our approval. It was visited in the process when we went out to set up our monitoring and we went out to look at the site, yes. In other words, the expectations of the approval process were very clear that the site would be visited and had to be visited before any experiment could take place because we had to set up the monitoring equipment.

Mr. VOLKMER. In order to do the monitoring, it was necessary to obtain some easements across the neighbors' yards and things like that. Is that correct?

Mr. SCHATZOW. That is something we did not realize at the time. That is something that became clear to us after we had visited the site. That was not clear to us at the time we initially——

Mr. VOLKMER. But it is going to be necessary?

Mr. SCHATZOW. That is correct at that particular site.

Mr. VOLKMER. Have those been obtained?

Mr. SCHATZOW. Not to the best of my knowledge, but you would have to check with AGS on that.

Mr. VOLKMER. For our future reference, do you see any desire to do anything different from what you did as far as site selection in this case as far as the future?

Mr. SCHATZOW. Again, I think very clearly, we are not in the business of site selection. It is the prospective registrant who selects his site and presents it to us. I think, again, there are some aspects to this whole proceeding that I think if we all had to do it over again, we would do it a little differently. I mean, we were constrained, I think, significantly in terms of the site because of the claims of confidentiality placed by the company on the site which limited a variety of things that we might have done.

Mr. VOLKMER. The other question I have in regard to what has been done is the question of the public's right to know that there will be such tests conducted. How do you envision that for the future?

Mr. SCHATZOW. I think there are two issues and two difficult issues involved here. One is the right to know and participate in the Federal process of granting the permit. I think that was a pretty open process this time because AGS did not claim most of the scientific information as confidential.

The second experimental use permit coming down the pike now which is a Monsanto application is being handled very similarly where Monsanto has claimed very little information as being confidential. So, we are going to be able to have a very open public process and opportunity for the public to comment.

So, I think our ability to do that will depend significantly on how much the company claims as confidential information in terms of the science.

I think the second part of the issue has to do with the specific locality where the experiment is going to take place. Again, I think that is going to be heavily dependent upon how the company handles that situation. I would hope and anticipate that in most situations the company would not ask for confidential treatment of that information and that the local public would be involved. I believe that is what is happening in the case of the Monsanto application.

Mr. VOLKMER. It is my understanding that that is going to be done on the property that they own in St. Charles County that is used as an experimental location, and that they informed the public through the media of their plan to be there, to be done there, which, by the way, happens to be in my district.

I really have no further questions at this time.

The gentleman from California.

Mr. PACKARD. Thank you, Mr. Chairman.

Let me pursue the site a little further so that I understand precisely how you will and have fit into that whole approval process.

You, after visiting the site, the EPA submitted amendments to the EUP. Those amendments granted or required written permission from adjacent property owners to the south and west, particularly. What was the specific purpose of requesting that written permission as a condition?

Mr. SCHATZOW. The way the site was set up at the corner of the property, there was a necessity of being able to go on adjacent

property to conduct monitoring that was required by the experiment. Second of all, there was a potential need to go on that property to treat with a microbiocide. Part of the condition of the permit was to monitor to see if there was any spread of the microorganism outside the confines of the site and, if there was, to treat it.

Since the way the site was set up, the area where that treatment would have had to take place and the area where some of the monitoring had to take place was on adjacent land not owned by AGS. So, we said in order to be able to carry out that part of your experiment, you obviously are going to have to be on somebody else's property and, therefore, we are requiring you to get a consent to enter form so that these people clearly have said that you are allowed to be on their property to do what you have to do there.

Mr. PACKARD. But access to the 5 acres is only on that piece of property? There is no other access to it, no other monitoring area?

Mr. SCHATZOW. I am not sure I follow you, Congressman.

Mr. PACKARD. Is that property that you have just referred to the only property where access and monitoring can take place? Is there not opportunity to approach the property or to do the monitoring on the north or on the east side?

Mr. SCHATZOW. Again, what we were requiring is that that kind of monitoring be done—if you look at the property—I think we have it in attachment No. 3 to the fact sheet—the requirement is that the monitoring and the potential for treatment be done on all four sides of the plot. So, that is what we are looking at, all four sides.

Is it possible that we could have only required it on two sides? I guess it is, but we felt it was appropriate to require it on all four sides.

Mr. PACKARD. And the land use on all four sides, what is the land use now?

Mr. SCHATZOW. I am not sure I know completely. I believe, again, that there is residential property on the south side. The south side is residential. The west side is pasture. The north side, I think, is their property, and I am not sure what the situation is on the east side. It is also their property for a significant length.

Mr. PACKARD. The intent of making these written permission requirements was to do monitoring and for accessability to the property and to the experiment?

Mr. SCHATZOW. That is right.

Mr. PACKARD. It was not to grant veto power to those adjacent property owners from the experimental position or from the work that is being done on the project? It is simply access and monitoring?

Mr. SCHATZOW. Well, in essence, in terms of this specific site, they have veto power. That is correct, because we have said that unless they agree to allow the company to enter, the experiment can't go forward. But if you are asking as a more general matter whether we would allow neighbors to have a veto power over an experiment, the answer is no, we would not.

Mr. PACKARD. If, for whatever reasons, the site were to be changed, either by choice of the company or because of not being

able to meet all the conditions, would that require the project to go through the application stage again? What would be necessary?

Mr. SCHATZOW. If an amendment was sought for a different site, we would review the specifics of that site. If there were no particular problems with that site, again, assuming we were where we were in November, we would approve it. Again, I don't think I want to comment until we have finished our investigation as to what would happen in terms of that specific issue.

Mr. PACKARD. Would they receive an approval from EPA for the project or for the experiment and the testing could be transferred to an appropriate site, whether it be this site or another?

Mr. SCHATZOW. That is correct, Congressman. Our approval, as I said before, was based on the experiment and our determination that it was a safe experiment. That determination that it is a safe experiment would be applicable on this site or most other sites.

Mr. PACKARD. And you have been satisfied that the concerns that have been expressed in the media and by others, whatever those concerns are, have been mitigated by the additional amendments and conditions placed upon the site?

Mr. SCHATZOW. Again, those concerns, the concerns as they relate to the site that we identified when we visited the site, which is the fact that there was not enough room on the site to do the kind of monitoring that was required in the permit, have been mitigated by the amendments to the permit. That is correct.

Mr. PACKARD. The original approval took into consideration the other expressed concerns, such as the environmental concerns and so forth?

Mr. SCHATZOW. That is correct, Congressman, yes.

Mr. PACKARD. Thank you.

Recognizing that this—and I think in your statement of facts, you considered this to be a low risk set of testing——

Mr. SCHATZOW. That is correct.

Mr. PACKARD. Let me transfer this discussion to your last point and that is the allegations relative to the rooftop incident. You consider that to be also a low risk test, as I recall you——

Mr. SCHATZOW. Yes. I mean, clearly, to the extent that we are comfortable enough with this organism, assuming the validity of the tests that we have received, to allow it to be sprayed in the open environment on strawberries, I think the answer is very clearly that we are comfortable enough to let it be inoculated into trees on the roof, certainly.

Mr. PACKARD. Had you been notified, you would have made perhaps no additional——

Mr. SCHATZOW. I am not sure of that. We would have had to look at that. Again, there are two issues. I think one is the issue raised before by the chairman which is whether the scientific validity is affected by being done in the outside environment.

I think the second issue that we would have had to look at was when you are looking at an experiment in order to determine pathogenicity, I have some concern about having that experiment being done in the open. We have the possibility, for instance, again, when you get disease, leaves can die, the wind blows them off the property. There are a variety of advantages to conducting that kind of ex-

periment to determine pathogenicity in a greenhouse rather than in the open environment.

Mr. PACKARD. So, you feel there was a violation of FIFRA?

Mr. SCHATZOW. I think there was very clearly a violation of our interim policy. Again, we all have an idea of what a contained facility is, I think, and laymen, I think, would agree that a tree does not meet that definition.

Mr. PACKARD. Does EPA have a responsibility to impose penalties when there are violations of their provisions?

Mr. SCHATZOW. Yes, we do.

Mr. PACKARD. And have you given any thought or any consideration to what type of penalty for this violation would be appropriate?

Mr. SCHATZOW. No, we haven't. We wouldn't do that until after we finished the investigation and figured out what all the facts were.

Mr. PACKARD. And is it true that this specific problem is in the courts, or is that something different?

Mr. SCHATZOW. The specific issue of this violation of the interim policy is not before the courts. The issue of whether the permit should or should not have been granted is before the courts.

Mr. PACKARD. Do you feel that your interim guidelines and regulations are clear and adequately outline the problems and the requirements of any company such as AGS.

Mr. SCHATZOW. On this issue I think it is very clear, yes.

Mr. PACKARD. As an aftermath of this whole incident and this hearing, do you sense or see that there will be a need to revise or to change your guidelines?

Mr. SCHATZOW. I don't see the need to revise or change the guidelines. I see a need perhaps for better public dissemination of the guidelines and better education of some of the scientists that are working in this area.

Mr. PACKARD. That was my next question. Do you believe that AGS was totally and adequately informed as to the requirements?

Mr. SCHATZOW. Well, I think AGS was clearly informed. They testified that they were. They submitted to us a notification and response to the interim policy. They were obviously aware of it at the corporate level, and, according to the testimony earlier today, their individual scientists were aware of it.

Mr. PACKARD. They were aware of it. Now, they did also testify that they actually discussed it at the decision making level as to whether they should notify EPA and they made a deliberate decision that it wasn't necessary.

Mr. SCHATZOW. That is what I thought I heard, too, Congressman, yes.

Mr. PACKARD. That brings up, then, that same question. Are the regs clear enough that it would avoid a repeat of this kind of an incident?

Mr. SCHATZOW. Well, again, I think what we—as I perceive it, what we have is the difference between a variety of people and some group called scientists and how they evaluate something that is written. I think any layman can look at something that says——

Mr. PACKARD. We are not talking about laymen here; we are talking about scientists.

Mr. SCHATZOW. Well, that seems to be maybe part of the problem. I am not sure. If you or I were asked when you read something in sequence that talks about laboratory, contained laboratory, growth chamber, greenhouse, or other contained facility, if you were taking your Miller analogy test and someone then said tree, you know, does that go in the same group, you or I would probably say I don't think so.

Mr. PACKARD. That was something I circled in your facts, and that was "or other facilities" and that——

Mr. SCHATZOW. Other contained facilities, right.

Mr. PACKARD. And that does leaving something undefined.

I think, at least speaking from my point of view, the primary objective of this hearing, and I may be presumptuous in making this statement, the primary objective of this hearing is to prevent these kinds of incidents from happening in the future. I don't think that we want any of our reputable experimental companies to find themselves in the same position that AGS is in. We certainly don't want to see this kind of incident reverse public commitment and government commitment to the kind of work that is being done. I don't think that certainly would be EPA's desires, either.

Which means that we need to find whatever mechanism is necessary to either better monitor, better inform, and educate, as you have mentioned, or certainly prevent misunderstandings that would put companies into the position that we find here.

Do you feel that you have been given completely factual and adequate and truthful information in the application for the approval of the strawberry testing that you have no concerns about the information that you have been provided in the application?

Mr. SCHATZOW. I think there are two different issues there, Congressman. I think the data that we received to support the AGS application evaluated by all the people who evaluated it raised no questions to any of the people who evaluated it in terms of the adequacy of that data and in terms of the validity of the data. So, there was nothing that we saw throughout the entire process that led anyone to say wait a minute, what happened here or how did they do this, or why did they do this, or I don't think they are telling us the truth. I don't think we had any of those questions.

Obviously, because of this rooftop situation, a question has been raised, and the Agency therefore believes it is only prudent, in this situation, to go back and review the validity of all the data.

Mr. PACKARD. What impact do you think this incident will have on the approvals of existing or future applications made by other companies that may want to field test genetically engineered organisms?

Mr. SCHATZOW. I think in terms of an EPA process, again, I am not sure what significant changes it is going to have in terms of the EPA process. I went through that process. I can't think of how we could have been more thorough, in the process we went through, to look at it.

I think the whole question of site is something that we are more sensitive to. I think the whole question of trying, although again we had difficulties in this case because of the claim of confidentiality, but trying to inform localities and involve local groups is something that we would try to look at in the future if we didn't have a

claim of confidentiality. But from an EPA perspective, I don't see very much changing.

Mr. PACKARD. I guess my concern is much more that when you are talking about an emerging technology which has a lot of public skepticism already surrounding it, the kinds of incidents that we have been talking about here cannot do that technology any good.

So, you basically feel that the existing regulations and the interim guidelines adequately address the issue and simply now it is a matter of following them and encouraging companies to understand?

Mr. SCHATZOW. Yes, I do.

Mr. PACKARD. I am pleased to hear that. What does—let me just briefly, and I don't want to dwell on this because, again, I don't think it centers on the central theme of what I would like to see come from the hearing. But, I sense that part of the confusion and misunderstanding of the rooftop incident came about over the containment issue. I have worked around greenhouses enough. In my area, the cut flower industry is a big industry, and much of it is grown in greenhouses of one sort or another.

Are greenhouses a fully contained environment in the sense that it prevents an escape of any pathogens or bacteria that you may wish to contain? In your judgment, do you feel that the greenhouse has a great deal more containment than the tree?

Mr. SCHATZOW. I think what we are dealing with, the notion of complete containment is a rather elusive concept, even when you get into the NIH guidelines and you start looking at the P-4, and you are talking about are they complete, absolute containment and can you guarantee that there is never going to be a release. I think the answer is pretty clearly not. So, I think we are talking about various levels of containment.

The notion of what can be both scientifically and economically appropriate levels of containment in terms of greenhouses is an issue that we are grappling with now, not just EPA but all the Federal agencies that are reviewing biotechnology. The Biotechnology Science Coordinating Committee, in fact, has just been meeting to discuss this issue and the possibility, for instance, of trying to come up with some greenhouse standards that might very well be somewhat parallel to the NIH standards for laboratories. I think it is clearly an important thrust and something that we are going to have to do.

Mr. PACKARD. Let me pursue one other avenue just for a brief moment. Do you think that this industry here in the United States is a leader in the world?

Mr. SCHATZOW. I believe it is. Yes, sir.

Mr. PACKARD. Do you believe that our current regulations, both interim and long-term regulations, that regulate this industry, genetic engineering, allow the industry to keep its preeminence world wide or does it tend to inhibit it? What is your response?

Mr. SCHATZOW. In terms of the kinds of provisions that the various agencies are talking about, in terms of what we at EPA are doing, in terms of the pesticide program, in terms of what we are talking about in TSCA, in terms of the OSTP document and the proposals in terms of how things would be handled, my sense is those are fairly reasonable proposals that provide adequate public

health and environmental protection but do not promote insurmountable roadblocks or very significant roadblocks in terms of the progress of the industry.

I am concerned about some of the potential amendments, Congressional amendments that are being talked about and what some of those might do in terms of providing much more significant roadblocks.

Mr. PACKARD. If those are implemented, do you sense it would tend to increase the exporting of this industry abroad?

Mr. SCHATZOW. I believe some of those would.

Mr. PACKARD. And you believe that would be significantly counterproductive to our own interests?

Mr. SCHATZOW. Yes, I do. Again, I am not suggesting any piece of legislation would be counterproductive, but some of what I have heard discussed as possible legislation sounds to me like it would be very counterproductive.

Mr. PACKARD. Thank you, Mr. Chairman.

Mr. VOLKMER. To continue on one thought that the gentleman from California had brought up and you discussed, do you believe that eventually you will be able to come up with more definitive statements as to what a contained facility is for certain categories or certain types?

Mr. SCHATZOW. I believe that, again, this is not a unique EPA issue and a unique pesticide issue, but I believe that the Federal Government will have to come up with—and we will do this through our Biotechnology Science Coordinating Committee—to come up with a notion of containment standards as they relate to greenhouses, different types of standards as they relate to greenhouses.

Mr. VOLKMER. As it relates to the type of possible release, also.

Mr. SCHATZOW. And the type of organism that is being tested. Again, one thing that we have to constantly emphasize about these two organisms that we are talking about here is these are well known organisms demonstrated in a variety of different situations not to be pathogenic. So, I mean, we are not talking about high risk organisms here when we are talking about the organisms involved in these experiments.

Mr. VOLKMER. Well, there is a difference between an organism that is definitely just a replica of a naturally existing organism which we know what it does or does not do and the creation of a new organism that is unknown, do we not?

Mr. SCHATZOW. Again, keep in mind that the parent strain is well known and there is a naturally occurring strain that is also an ice-minus strain. The point is these are not exotic microorganisms. Within the land of microorganisms, these are very well known and identified and a lot is known about them.

So, the kind of containment that one might want, for instance, in terms of a greenhouse standard for this would not be the kind of containment that we now have at Fort Dietrick for some of the pathogens that the Army is testing, for instance. It is a little different.

Mr. VOLKMER. I agree on that. The other thing before we close, Mr. Schatzow, and I appreciate your being here today and certainly look forward to the full investigation and the determination being

made at that time, but one thing I want to make clear, I think, also, is that I see, again, as I said in my opening statement, the field of biotechnology in this area is one that we need to continue. I think it shows great promise in the future.

On the other hand, I don't want to go down the same road that we went with other things that we have developed, chemicals, et cetera. You understand my concerns.

Mr. SCHATZOW. I certainly do.

Mr. VOLKMER. And the concerns of some of us in the Congress. We don't want to go down that road. We want the public to know that when it is brought out, it is safe. They don't have to worry about it. That is all we want.

Mr. SCHATZOW. And we share that same concern.

Mr. VOLKMER. All right. Thank you very much.

Mr. SCHATZOW. Thank you, Mr. Chairman.

Mr. VOLKMER. Dr. Robert Colwell, professor at the University of California at Berkeley, and he also was on the panel that approved, the ad hoc sub-panel of the science advisory panel for this and also testified back in December. We welcome you back again.

Before we begin, along with all our witnesses, Dr. Colwell, do you swear to tell the truth, the whole truth, and nothing but the truth, so help you God?

Dr. COLWELL. Yes, I do.

Mr. VOLKMER. Thank you very much. Dr. Colwell, as I understand it, you do not have a prepared statement typed up and ready to go on the record, but you do have a short statement.

Dr. COLWELL. I have a short statement, yes.

Mr. VOLKMER. I would appreciate your proceeding.

Dr. COLWELL. Thank you, Mr. Volkmer.

STATEMENT OF ROBERT COLWELL, PROFESSOR, UNIVERSITY OF CALIFORNIA AT BERKELEY, BERKELEY, CA

Dr. COLWELL. My name is Robert Colwell. I am a professor of zoology at the University of California at Berkeley. I teach ecology and evolutionary biology. My research focus concerns relationships between insects and mites and their host plants and pollination biology.

I have acted as an unpaid consultant to NIH, EPA, USDA, and OECD on matters involving the release or testing of genetically engineered organisms in the environment.

I also, at the request of State Assemblyman Sam Farr of the California legislature, attended and testified at the January meeting of the Monterey County Board of Supervisors and, at that meeting, testified that I considered the test that AGS has proposed to be safe and that the committee that reviewed it had agreed that it was a safe test.

Also, I do want to apologize for not having a written statement, but I was asked to testify yesterday when in Washington on other business, and I didn't have time to prepare anything.

As an ecologist who studies population dynamics and interactions between species and biological communities, it is clear to me that the testing and eventually the commercial use of genetically engineered organisms in the environment is neither categorically

dangerous nor categorically safe. There is nothing in the AGS case that has changed my mind on this general issue whether or not it turns out to be true that the AGS ice-minus organisms are pathogens of rosaceous fruit trees.

The purpose of the EPA review prior to testing genetically engineered organisms in the open environment is to permit disinterested scientists from a carefully chosen set of disciplines to evaluate each case for the safety of the proposed test and for the benefit and protection of society at large. It is impossible to carry out this task without full and detailed disclosure of all relevant information by the applicant. If the judgment of safety, and what results are important, is made ahead of time by the applicant, this process is derailed.

From my own point of view, I am very concerned and troubled by finding out that what we believed to be true in reviewing the case on the basis of submissions to EPA has turned out not to be accurate.

First of all, the issue of remoteness. The panel was assured in writing in several places that the test would be carried out in "remote locations," remote from crops, remote from fruit trees. This is not true. We simply didn't look and demand to look at the test site because of the assurance of the company that it would be a remote site.

I feel personally bad about it since I am the closest member of the committee to the site. I could have gone down and looked at it if I thought there was any doubt, but I assumed that by remote they meant something much different from what it turned out to be.

Second, we have the issue of the rooftop experiments. In their application for an EUP, I want to read you two statements. This is for the pathogenicity testing: "Plants were incubated in a greenhouse at approximately 21 plus or minus 5 degrees centigrade on elevated benches without misting or under moist conditions as recommended." No qualification for some of them being out of the greenhouse on the rooftop in different temperatures.

Footnote to table 1f. Table 1f is entitled "Inoculation Methods for Tests of Pathogenicity to Plants." The first line in the table is branch injection of cherry, peach, apricot, plum, almond, and pear. There is a footnote to the entire column of inoculation including this that says "Plants were incubated on greenhouse bench and/or under moist conditions at 21 plus or minus 5 degrees centigrade as recommended by referenced publication."

Now, the only possible escape from, I would say, intentionally misleading the panel is the "or" under the slash in the "and/or." However, it does state clearly that it was 21 plus or minus 5 degrees centigrade. I live in Berkeley. In February of any year, it goes much colder, and this year, it went up to 80 degrees. There is no way that that indicates to anyone reading this that those are anything but greenhouse conditions.

I won't speculate on the motivations of the company for not reporting that they did this on the rooftop. All I can say is that every member of our committee and everyone at the EPA who read the report assumed that these tests were done in the greenhouse.

That brings up two issues. The first is: Did any harm come of doing them on the rooftop? Well, if it is true that they weren't pathogenic, then I feel no hesitation in saying that no harm came from it. However, assuming that they aren't pathogenic and then saying it is OK to do it on the rooftop because we know they aren't pathogenic when you are testing pathogenicity just doesn't fly in terms of logic.

In fact, in the statement of AGS today, in their written statement, we find this sentence about the workers in this project, "They were confident that the test organisms were not pathogens and therefore would not multiply in the fruit tree tissues." One might well ask why they are doing the test if they are already confident that they are not pathogens.

The second issue that comes up, having discovered that things were not as we thought they were, is we wonder what other things were not as we thought they were. This is only normal human behavior to become doubtful about this. Hopefully, EPA is looking into those doubts, because I am sure they have them also.

The document that you revealed this afternoon from whoever wrote it obviously adds further doubt. If it turns out that indeed they are pathogens of fruit trees, then, obviously,—I hope obviously—no one on our committee nor at the EPA would have recommended using these as treatments, widespread treatments eventually, widespread treatments for strawberry plants even in areas that are not commercial producers of fruit trees. People have fruit trees in their back yards. Everybody does in California, and it wouldn't be a very good idea.

Even worse than that is the prospect, if it turns out that they are pathogenic, that they might have been used as treatments for fruit trees. In the documents submitted to EPA, there is also a section on colonization of flowers of the same species of fruit trees. They are intended to prevent flowers of strawberries from freezing. In fact, the original organisms that were then modified were taken from strawberry blossoms.

They are not pathogenic to strawberries, according to the data submitted, and they didn't harm the flowers of the fruit trees that were tested, but we find in AGS' statement—no, AGS passed out this document at the Monterey County Board of Supervisors saying that "knowledge gained from this test will be directly applicable to frost protection of other crops such as almond, peach, cherry, and pear."

So, I would be very eager to have much more widespread tests done before any scale-up even if this current experiment is done. I would want to see much more than one tree per treatment, one replicate tree per treatment, tested. If they used 50 trees, it takes 45 trees to have exactly one individual tree per treatment, given all the varieties they tested. It is not a very large sample size.

That is the end of my statement.

Mr. VOLKMER. Thank you very much, Dr. Colwell.

Of course, I believe you have already commented on this, but in the data that was submitted to EPA from AGS, there was nothing in there showing that the ice-minus bacteria, the various types that they used, caused cankers in the fruit trees.

Dr. COLWELL. On the contrary, it was stated clearly and several times that they did not.

Mr. VOLKMER. They did not, right.

Dr. COLWELL. Except for the positive controls.

Mr. VOLKMER. Right, but their statement also shows that before they ever ran the test that they had that opinion that there wouldn't be any.

Dr. COLWELL. It says that in their written statement today.

Mr. VOLKMER. And is it not true that anyone knowing it, if any fruit trees showed any pathogenicity from the ice-minus type of bacteria that was used, lo and behold, everybody agrees that it is never going to be used.

Dr. COLWELL. I would agree with that. Perhaps they could find a strain that was not pathogenic to any plant that is common in the areas that they are using. That is, of course, what we thought they had done, and, until there is further investigation, I will assume that they did do.

Mr. VOLKMER. Do you feel that basically as a person who reviewed this data—I assume you do from your statement—that you were kind of led a little astray?

Dr. COLWELL. Yes. I can only say that. Perhaps it is my naivete. That is possible, but it would have to be the naivete of everyone else on the committee plus EPA if that is the problem.

Mr. VOLKMER. Basically, we read basically the same statements that you did in AGS' statement to EPA about the controlled conditions, et cetera.

Dr. COLWELL. Yes.

Mr. VOLKMER. And yet they knew definitely that they conducted these tree experiments on a rooftop in the open air.

Dr. COLWELL. Who knew that?

Mr. VOLKMER. AGS knew that.

Dr. COLWELL. Oh, of course they did, yes. Also, I just remembered something else.

Mr. VOLKMER. And there is nothing in their data submitted to EPA that said that.

Dr. COLWELL. No, not a thing.

I wanted to comment also that Dr. Bedbrook said also that it is not necessary to report where the tests were done. Anyone who wanted to repeat those tests, which is a quality that should be in every scientific paper, repeatability of the experiments, could not do so without knowing where they were done. To say it doesn't matter to a plant whether it is growing in a cold and windy environment with rain, which is what we have in February, versus a warm greenhouse with a mister is simply naive. I mean, it is very important to the plant's health and the state of its physiological systems.

Mr. VOLKMER. Let me give you something else that bothers me a little bit, and I hope that EPA is looking into it if it is accurate.

That is, according to the information that we received in this communication, there were actually eight different types of what I would call the sera, the bacteria or the no bacteria type of thing. There are actually 8 in a total of 50 trees.

Dr. COLWELL. I came up with five somehow.

Mr. VOLKMER. Inoculates, let's say.

Dr. COLWELL. Sorry; it is six in some cases. For *Pseudomonas syringae,* there would have been the positive control, the negative control, the parent strain, and the—if there is a positive control, there have to be six at least.

Mr. VOLKMER. Here is what we were given, and I forgot to ask Dr. Bedbrook if this is correct. I will probably call him back because he is still here to find out if this is correct, that they had a *Pseudomonas syringae* ice-nucleation positive, and *Pseudomonas syringae* ice-nucleation negative, a *Pseudomonas fluorescens* ice-nucleation negative, a *Pseudomonas fluorescens* ice-nucleation positive, a *Pseudomonas syringae* pathovar which is a positive control, then another one which is a buffer control, and then a *Pseudomonas syringae pv. syringae* control——

Dr. COLWELL. Well, I think altogether there should be six, at the maximum, treatments counting the negative control, the positive control, and four kinds of bacteria, parent and—I mean, this is what is reported in the AGS document. So, there is a negative and, in some cases, a positive control if they could get a strain for that. In all cases there is a negative control with just the salt solution and then four kinds of bacteria, two parent strains and two engineered strains.

Mr. VOLKMER. OK. Again, I am not a plant pathologist, but as I understand it, they injected these on the branches of the trees. Therefore, they probably put them in different branches of the same trees.

Dr. COLWELL. Well, they must have if they had any replication with only 50 trees and 8 varieties and 5 tests, because that comes up to 45 at least. It is about 50, about 1 tree per treatment.

Mr. VOLKMER. Well, we want to make sure we communicate our concerns about this to EPA also when they look into the methodology as far as——

Dr. COLWELL. Yes; I see on the thing you handed out that there are three varieties of almonds listed and there is only one in AGS data.

Mr. VOLKMER. Yes, correct.

Dr. COLWELL. So, I assume EPA will look into that.

Mr. VOLKMER. Yes.

Dr. COLWELL. What those other varieties did, what they did with them.

Mr. VOLKMER. Is there anything else that we have gone over or in this document that may concern you?

Dr. COLWELL. There is just one statement also on page 16 of the AGS document that one of the reasons they weren't concerned about the problem of doing them in the open environment was that AGS strains are taxonomically distinct, which is to say they belong to a different evolutionary lineage than the pathogenic strains of that species, and therefore wouldn't multiply in the fruit tree tissues. One of the problems in the original submission in their notification of intention to test was that it wasn't clearly identified. There was a whole battery of tests that EPA asked them to do in January 1985 in order to identify the exact pathovar that they had.

It is a little bit hard for me to see how they knew in February a couple of weeks later without yet doing those experiments that it

was totally distinct, but that is just something that I hope EPA would look into.

One other thing that I wanted to mention that sometime your committee might want to look into, and it is not particularly to do with AGS although they, as in many other, no doubt, laboratories, do this, and that is to—because of the effluent problem, because of bacteria getting into the effluent, one can ask whether any of the engineering that has been done to those bacteria will have an effect in the sludge and sewage treatment environment once it reaches there.

There is a very well known fact that pieces of DNA from bacteria are transferred by plasmids and by other means sometimes between bacterial species. In the case of the AGS organisms and many other proposals for field testing, the way the organisms are found once they are released is through antibiotic markers. The AGS organism appears to have three of these. Those antibiotic resistant genes, then, go down the tubes with the bacteria and into the sludge treatment plant and is a possible point of transfer to other species.

The antibiotics, I think, are not important in human treatment, but this is something that I am concerned about as an ecologist.

Mr. VOLKMER. Thank you very much.

Mr. Packard.

Mr. PACKARD. Thank you, Mr. Chairman. I don't have a lot of questions.

I have been aware all along that scientists have certainly different views of scientific research, particularly when it comes to proprietary projects themselves. I think they can differ and often find criticism in one another's approach and methodology, and I sense that I am hearing that today.

If you were conducting such an experiment or testing, would you have suggested that it be done in a more contained environment? For example, one of the criticisms has been that they did it in the open.

Dr. COLWELL. Yes, I would. As a person who studies both birds and insects, there are insects and birds who use sap flows from trees as part of their regular diet, so they would go from one sap flow to another. If they happen to have gone from a sap flow on the roof to a sap flow in someone's yard, they might have carried the bacteria.

Mr. PACKARD. At the same time, you have expressed concern that it has only been on 50 trees, and 50 trees occupy a substantial space.

Dr. COLWELL. That is true.

Mr. PACKARD. One that probably would exceed most greenhouse facilities and would certainly raise the cost of constructing facilities to accommodate an experiment that would be four, five, or six times the number of trees. Is there some inconsistency in requiring or expecting this to be done in a greenhouse environment and yet still have it broad enough that it will be of orchard proportions?

Dr. COLWELL. Well, I am afraid I am not very sympathetic to the argument that it costs too much to put the trees in greenhouses for an industry that hopes to make millions and millions of dollars off their products.

Mr. PACKARD. Well, I don't think that their annual report has reflected that they are making millions——

Dr. COLWELL. Not yet, but they hope to.

Mr. PACKARD. If we don't bankrupt them before they can get to that point.

The remote issue, where does the requirement of remoteness come into play or is it a requirement?

Dr. COLWELL. It is not a requirement, and that was correctly stated by EPA. However, there was the assurance of the company that it was a remote site, a site remote from crops, a site remote from fruit trees, in their own words.

Mr. PACKARD. So, the comment or the statement came from AGS.

Dr. COLWELL. That is right. It was a voluntary statement on their part. I mean, that was earlier and, apparently, they changed their minds, but they didn't tell us that, and I feel I am misled by that.

Mr. PACKARD. What would you consider remote?

Dr. COLWELL. There are plenty of places in California that are many miles from the nearest house, for a start, where one could grow strawberries. There are places that are remote from fruit trees, if that is a particular concern, and also from strawberries.

The problem is it has to be done in a place where the conditions are at least something like the conditions would be in a commercial application or it is a meaningless test from the company's point of view, and I am very sympathetic to that. But I think they could have found a place in a strawberry growing area or a place that at least strawberries could be grown adequately to test this, that would have not been in somebody's back yard, if that is what it turns out to be.

Mr. PACKARD. Again, I think it has been made clear that this whole question of remoteness would not have been an issue had they not voluntarily indicated that they would look for a remote site.

Dr. COLWELL. Well, I think you will hear in a few moments it would certainly have been an issue with the people in Salinas.

Mr. PACKARD. That well could be the case, but that may not be a criterion that is a justifiable criterion.

Dr. COLWELL. No; it may not, not from a scientific point of view. That is correct.

Mr. PACKARD. From a scientific point of view and from EPA's point of view, it is not a requirement.

Dr. COLWELL. That is right, but I think—I have this feeling that in the future companies are going to be watching this very carefully and they will make an effort to find sites that are not so close to where people will be concerned. I think that is good. That is a good outcome from this. The other good outcome is that there will be more care taken to give full and complete detail of how tests were done.

All of those things are good, and I am sorry it had to happen this way to have that happen. I don't think any harm has been done to the environment, as long as the data are correct, and I would not oppose the doing of this test as long as the data are correct that are in the original application.

Mr. PACKARD. I have no further questions or comments, Mr. Chairman.

Mr. VOLKMER. Thank you very much, Dr. Colwell. I, too, agree with you that if the data all proves out and everything in the tests prove out that they were valid tests, even if it was done on a rooftop, et cetera, and no further tests are necessary. That is the judgment of the people who are knowledgeable, the scientific experts on it, and I can see it proceeding somewhere. Now, whether it is going to be at that site or not is another question, but on the other hand, I, too, am really, like you, just a little bit dismayed that all of this has occurred.

In my opinion—I may be wrong, but in my opinion basically the people at AGS just substituted their judgment for EPA's as far as using this rooftop open air-type of thing to prove pathogenicity.

Dr. COLWELL. I would be very pleased if companies would look at the EPA review as an opportunity to get, for free, a tremendously valuable set of professional opinions about the ecological aspects of their experiment from a highly qualified set of experts which they can then put to good use. But we cannot do it unless we have all the data. That is the lesson from this.

Mr. VOLKMER. All right.

Mr. PACKARD. If the chairman would yield, I think that if I heard the testimony correctly, AGS admitted that in retrospect, looking back, they would have made their decisions differently than they did. I think they said that, but I don't think we ought to imply that they did not deliberately and carefully evaluate what direction they were going.

Now, they did not project where that would lead them.

Dr. COLWELL. I have every hope that that is so. My confidence is shaken by finding out that things were not true that I believed to be true. You can only understand that, I am sure.

Mr. VOLKMER. Thank you very much, Dr. Colwell.

Our next witness will be Mr. Sam Karas, chairman of the Monterey County Board of Supervisors. He is accompanied by Mr. Walter Wong, director of environmental health of Monterey County. And we have now our very illustrious colleague and good friend of everybody here and outstanding leader in the House of Representatives, the Honorable Leon Panetta. We will start with the gentleman from California.

STATEMENT OF HON. LEON PANETTA, A U.S. REPRESENTATIVE FROM THE STATE OF CALIFORNIA

Mr. PANETTA. Thank you, Mr. Chairman.

Mr. Chairman, Mr. Packard, I appreciate first of all your having this hearing on this very, very crucial issue and appreciate your taking the time to look into this issue. This is a very important one, and it hit home particularly in Monterey County when we faced the issue of whether or not we would allow for that kind of open field testing in the county. For that reason, I am pleased to have the chairman of the Monterey County Board of Supervisors, Sam Karas, here who is accompanied by Walter Wong, the director of environmental health, so that they can give you a first-hand view of what took place in this particular situation.

I also want to express my gratitude for allowing the president of the Monterey citizens organization, Glenn Church, the opportunity

to testify, because he also became involved from the citizens' point of view.

Let me just ask that my testimony be made part of the record, and I will try to summarize it.

The issue of biotechnology experimentation, obviously, is something that I think all of us have to focus on. There are rapid developments taking place in this field. They have taken place over the last several years. They have raised concerns among the public. Obviously, they are of concern to the scientific community, and they have to be of concern to government at all levels.

While this relatively new technology holds a great potential for improving, I think, the quality of life on our planet, I think it also presents an enormous challenge to all of us to ensure that what we do in this area provides for public safety and public information.

There are several lessons that I would like to share with you that we learned first-hand in Monterey County as a result of this experience with the effort to have open testing there, and I think they are lessons that I hope the subcommittee will look at in terms of your approach to dealing with this issue.

The first is, I think, that we have to recognize that the fundamental reason for our nation and, indeed, our civilization's advance lies in our drive to discover new methods of improving the conditions under which we live. Obviously, despite the problems that I know you have been made aware of today, I hope and I have no doubt, that we will continue to encourage research into safe and effective ways to improve agricultural production along with other efforts to try to improve benefits for both consumers as well as those in agriculture.

The second lesson is that such research has to be conducted under conditions that protect the public safety and minimize health risks. If in fact there are concerns about the impact on health and welfare, then we have a responsibility at the public level to make sure that we minimize those risks.

The Frostban experiment in our county is a good example of where we ran into a problem. An experimental test permit, as you know, was provided in Monterey County. The EPA recommended that the area be isolated because of the concern about releasing the organism, and then rather than visiting the site directly, what happened was that eventually EPA found out, as did the county, that the experiment was to be conducted near a residential area in north Monterey County.

There are areas of the county, I might point out, that are more isolated and, I think, would have been more appropriate for such an experiment. But the action ran contrary, I think, to the kind of conditions that even EPA had put down on the subject.

Now, I recognize that EPA issues permits for literally thousands of pesticide experiments and that it would be difficult to go out into the field and evaluate each of these. But given the uncertainties involved with this new technology, and this was the first test to take place in an open field, EPA I think, should have proceeded with greater caution and should have had a site evaluation of the test itself.

So, obviously, the lesson that I think is drawn here is that conditions imposed on such experimentation must be met both in spirit and in substance.

The third lesson is, I think, there is an immediate need for us at the Federal level to clarify and coordinate the Federal structure involved in this area. There are four or five different agencies involved with biotechnical developments of one kind or another. We have USDA involved in it. We have EPA, we have the FDA, we have the National Institutes of Health. There are just a number that are dealing with this issue and, very frankly, there are really not consistent policies among these various Federal agencies that have jurisdiction to deal with this issue.

There is a confusing maze of Federal bureaucracy that now governs aspects of biotechnology that I think is unnecessarily cumbersome. Manufacturers are frustrated. Concerned citizens are frustrated in their efforts to obtain information on the hazards of such experiments. In response to these concerns, both State and local governments have been frustrated in their efforts to provide guidance on this matter.

So, I think it is essential that we at the Federal level try to develop a cohesive Federal policy with regard to this area.

The fourth and perhaps the most important lesson, that I think, I want to share with you is the fact that where a new substance and a new experiment like this is involved, and where it is shown that it might involve some risk to the public, the public has to be fully informed of the risks as well as the monitoring steps needed to take to minimize those risks.

There is a tendency among the scientific community, and I think it sometimes afflicts those of us in government as well, that somehow they know best and that the public need not be fully informed, that they are trying to protect the public safety, that they have the safety in mind. And they believe there is no danger in the experiment, and I respect their sincerity in that belief. But the public has a right to be informed.

Here, in the Monterey County situation, there was a failure of both the public and private agencies to fully advise local officials and the community of what was involved. Knowledge, as we know, I think, is the best cure for fear, if indeed the knowledge confirms that there is nothing to fear.

This may or may not have been the case here because there simply is not enough information available to ultimately make that determination.

I think those are the lessons that I would recommend to all of you from the experience that we had in Monterey County. If we can learn those lessons that I have outlined, then I think we can benefit from the mistakes that have been made in this area.

We have to do the following: There has to be coordinated and consistent policy direction established among the responsible Federal agencies in this area. Second, EPA guidelines for experimentation must be strictly enforced and monitored and adherence to safety regulations must be implemented in both spirit and substance. Three, notwithstanding the need for confidentiality of business operations, which I understand and respect, the public's right to know must be given the first priority, whatever change in atti-

tude this may require in both the government and scientific communities.

Again, I want to thank you for this opportunity. This has been an experience which I think all of us hopefully can benefit from.

[The prepared statement of Mr. Panetta follows:]

STATEMENT OF HON. LEON E. PANETTA
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
MARCH 4, 1986

I want to thank the Subcommittee for holding this hearing and providing me with an opportunity to testify on this critical subject. I also appreciate your giving the Chairman of the Monterey County Board of Supervisors, Sam Karas, who is accompanied by Walter Wong, the County Director of Environmental Health, and the President of a Monterey citizens organization, Glen Church, an opportunity to testify.

The issue of biotechnology experimentation was brought most forcefully to my attention a few weeks ago, when Advanced Genetic Sciences, Inc. (AGS) was given a permit by the Environmental Protection Agency for an experimental use of "Frostban" on a strawberry field in Monterey County, in my Congressional district. The controversy raised by the events surrounding that proposed experiment has national implications and has led in part to this hearing.

The rapid developments in the field of biotechnology over the past several years have raised enormous concerns for the public, for the scientific community, and for government at all levels. While this relatively new technology holds great potential for improving the quality of life on our planet, it also presents many risks, some of them potentially enormous and without precedent to guide us.

Our knowledge of the short- and long-term effects of this kind of experimentation for human, animal, and plant life remains limited. It is clear that the careful regulation of these activities must be given a high priority by local, state, and federal governments. The federal government is ultimately responsible for this national issue, but state and local governments have a key role to play as well. The En-

vironmental Protection Agency has a clear and serious responsibility to work with state and local agencies, as well as the public, to provide for safe experimentation that is as risk-free as possible.

In the case of Frostban, there was no formal notification to the public or to local government that this experiment would take place. The Monterey County Board of Supervisors was not briefed by the EPA until the Board raised strong objections based on legitimate concerns raised by members of the community. These legitimate concerns were primarily over the safety factor. The fact is that EPA had approved a permit for a potentially dangerous experiment in a part of the county that is very close to a populated area. Frankly, EPA treated this new substance as if it were a routine pesticide when it was clear that a higher level of caution was called for. This, combined with the lack of consultation, caused a public reaction which eventually convinced the manufacturer to delay the experiment and move the site to an unpopulated area. These events could be used to write a primer on how not to regulate these experiments.

When all of the evidence is considered, there will be four very important lessons from the experience with Frostban. These are lessons that we seem to be taught over and over again but fail to learn.

First, a fundamental reason for our nation's, and civilization's, advance has been our drive to discover new methods of improving the conditions under which we live. One of the most important, of course, is the quantity and quality of the food we eat. Despite the problems we are discussing today, I hope - and have no doubt - that we will continue to encourage research into safe and effective ways to improve agricultural production, including possible methods of controlling

frost damage. Improvements benefit both consumers and agriculture. The lesson here is that we must encourage research and development and provide cooperation and coordination between the private and public sectors to ensure safe and effective ways to achieve that goal.

The second lesson is that such research must be conducted under conditions that protect the public safety and minimize health risks. Experiments conducted to improve the public's health and welfare cannot at the same time jeopardize the public's health and welfare.

A case in point is the Frostban experiment. Despite precautionary conditions that the EPA required for this potentially dangerous field test, the EPA's own Hazard Evaluation Division concluded that the new microbe would probably escape the strawberry experiment and could survive indefinitely on plants outside the experimental plot. As a condition for issuing the experimental test permit, the EPA recommended that the area be isolated from a populated area in order to protect against the spread of the microbe, as well as a requirement that protective gear be provided to the individuals conducting this experiment. It was not until after the permit was granted that the EPA actually visited the site, and it was only then that the Agency learned that the experiment would in fact be conducted near a residential area in North Monterey County. There are areas of the County that are more isolated and would have been more appropriate for such an experiment. This action alone ran contrary to ideal conditions recommended for the experiment by the EPA. I recognize that the EPA issues permits for literally thousands of pesticide experiments and that it would be difficult to go out in the field and evaluate each and every site. However, given the uncertainties involved with this new technology, EPA should proceed with even greater caution, and site

evaluation should be an integral part of the process.

EPA's own recommendation stated that such field tests should be conducted in remote locations, away from people and crops. The EPA even required that protective gear be provided to the individuals conducting this experiment. Clearly, the neighboring landowners should have been afforded the same protection by restricting the site to a remote area. The lesson here is that conditions imposed on such experimentation must be met both in spirit and in substance.

The third lesson is that there is an immediate need to clarify and coordinate the federal structure for the safe regulation of new, emerging biotechnologies. We must have consistent policies among the numerous federal agencies with jurisdiction over this area of experimentation. The confusing maze of federal bureaucracy that now governs aspects of biotechnology is unnecessarily cumbersome. Manufacturers have been frustrated in their efforts to discover the proper regulatory procedures to work through; concerned citizens have been frustrated in their efforts to obtain information on the hazards of such experiments; and in response to these concerns, both state and local governments have been frustrated in their efforts to provide guidance on this matter - due to a lack of cohesive federal policy. The federal agencies charged with regulating these new substances must develop safe and consistent policies that will provide effective guidance to those individuals and organizations affected by this technology.

The fourth and perhaps most important lesson is that in such experiments, where a new substance is involved and where it is shown that there is some risk to the public, the public should be fully informed of the risks, as well as monitoring steps that will be taken to

minimize those risks. There is a tendency among the scientific community, which sometimes afflicts government as well, that they know best and that the public need not be informed. They believe that there is no danger involved in the experiment, and that therefore, there is nothing for the public to be concerned about. But the public has a right to be informed. Here, there was a failure of both public and private agencies to fully advise local offices and the community of what was involved. Knowledge, as we know, is the best cure for fear - if indeed, this knowledge confirms that there is nothing to fear. This may or may not have been the case here, because there simply is not enough information available to make that determination.

Regarding Frostban, it is possible that research can proceed, but only with appropriate protections for public health. In addition, action must be taken to fully inform the public of any risks involved.

More broadly, if we can learn the lessons that I have outlined here, then we can benefit from the mistakes that have been made in the past. We must do the following: 1) There must be a coordinated and consistent policy established among the responsible federal agencies to provide guidance and information to state and local governments and the private sector. 2) EPA guidelines for experimentation must be strictly enforced and monitored, and adherence to safety regulations in both spirit and substance must be insisted upon. 3) Notwithstanding the need for confidentiality of business operations, the public's right to know must be given the first priority, whatever change in attitude this may require for both government and the scientific community. These should be the guiding principles for any new policies implemented by Congress or the Environmental Protection Agency.

Again, Mr. Chairman, thank you for this opportunity to testify.

Mr. VOLKMER. Thank you very much, Leon.

Mr. Karas, you may proceed. I have reviewed your statement, and that will be included in the record at this point in the record in full. You may review it in full or summarize, however you so desire, and I want to welcome you here today and thank you very much for coming.

Mr. KARAS. Thank you very much, and I want to read for the record.

Mr. VOLKMER. Go ahead.

STATEMENT OF SAM KARAS, CHAIRMAN, MONTEREY COUNTY BOARD OF SUPERVISORS, MONTEREY, CA, ACCOMPANIED BY WALTER WONG, DIRECTOR OF ENVIRONMENTAL HEALTH, MONTEREY COUNTY, CA

Mr. KARAS. Also, with your kind indulgence, we separated into two divisions. I am a layman. Mr. Wong is a technical man, and I guarantee we won't go over 10 minutes.

Mr. VOLKMER. That is quite all right.

Mr. KARAS. I would like to take this opportunity to thank you for allowing us to participate in this vital hearing.

The first outdoor testing of genetically engineered bacteria has focused world wide attention on Monterey County. I can tell you, Mr. Chairman, how important this issue is is evidenced by the mass media coverage throughout our Nation and Europe. I am constantly at my office being called from all over Europe and every newspaper in the United States. We have received telegrams from members of the West German and European parliaments stating their opposition to the project.

There are various issues involved in allowing this project to go forward. I think, Mr. Chairman, one of the most major issues is that in a democracy like ours, citizens have a right to know when a decision is made which can potentially affect their health and safety.

Can I just deviate for 1 second? It is my first visit to Washington, and I want to tell you it really struck home to me that this is a democracy of the people, for the people, and by the people, and I think that really pertains to that paragraph.

This is not to say that the procedures followed by the EPA or the State department of food and agriculture were deliberate attempts to keep the experiment shrouded in secrecy, but their actions aroused a great mistrust on the part of elected officials as well as the public. Failure on their part to notify us of an experiment of such national, if not world wide significance, is unconscionable.

Prior to the issuance of the permits by EPA or the State department of food and agriculture, no public official in the jurisdiction most affected was notified. Never were we involved in the approval process by these agencies. If it were not by a petition signed by local concerned citizens, like Glenn Church who will testify later, experiments probably would have gone forward without any regard for due process.

It is hard for me to believe that the State department of food and agriculture or the EPA would treat this unusual experiment as a routine one. In fact, Dr. Bedbrook said it was a unique experi-

ment. But judging from their actions, this appears to be what occurred.

They were aware that by placing the designation of pesticide on this project, no environmental impact report would be needed to be furnished and those agencies would retain regulatory powers rather than allowing local governments to become involved. By their failure to apprise Monterey County of this project, the EPA and the State department of food and agriculture have created a great public mistrust of any future decisions—and I mean that sincerely—that they may make regarding our county.

It was at this point that we supervisors felt that the only way to clear the air was to hold a public hearing. So, on January 27, 1986, a public hearing was held where testimony was received from government officials representing EPA, the California State Department of Health Services, Food and Agriculture, as well as from Advanced Genetic Sciences, a number of scientists, and the Foundation for Economic Trends, and concerned members of the public.

During the hearing, it came as a rude shock to learn from Fred Betz of the EPA that no on-site inspection of the testing area was ever done. The Agency was not aware that the site was not located in a rural area but within one-half mile of a residential area which is near 10,000 people. Never during the testimony did the EPA state that they would assume any financial liability which we consider crucial to the issue.

As far as we are concerned, the issuance of the permit by the EPA is highly questionable. As a result of the testimony we received at the hearing, it was evident that there was a lack of necessary information on which to base any decision.

We decided to adopt an interim ordinance banning any experiments in our county for 45 days. By taking this action, we allowed ourselves additional time to arrive at solutions to this important problem.

For your information, the ordinance prohibits any field experiment in Monterey County using genetically altered bacteria. It is our legal counsel's opinion that the bacteria is of an animal origin. Thus, it should be subject to land use regulations. This action gives Monterey County, not the State department of food and agriculture, complete regulatory powers.

To help clarify some points that may occur to you, Mr. Wong and I did visit the Advanced Genetic Sciences laboratory in Oakland. In all honesty, we were given a tour of the facility and we were impressed with the dedication and professionalism of its employees.

During our visit, we met with key personnel involved in the Frostban project, and we found them extremely cooperative and willing to answer our concerns. At this meeting, we requested more information regarding the testing and were assured the answers would be forwarded to us. We are presently awaiting those answers.

In the meantime, we were surprised to learn via a newspaper release in the Washington Post that a test of Frostban had been made on the roof of their headquarters in Oakland during the period of February to June in 1985. No mention had been made to us of such an experiment. It made us wonder if they had been as candid and frank with us as we thought.

On February 20, Mr. Wong, director of environmental health, Mr. Ralph Kuchler, our county counsel, and I traveled to Sacramento to discuss this issue. At that meeting chaired by Assemblyman Sam Farr were officials from the Department of Commerce, Health Services, Food and Agriculture, and the chairman of the Governor's Interagency Task Force on Biotech Industry. The meeting was productive, and a great many of our concerns were addressed.

Financial and health liability, procedure and regulation processes, and a proper method of notification were some of the concerns that were resolved to the satisfaction of all parties. However, we were advised by the Department of Food and Agriculture that if we invoked a permanent ordinance banning such testing, they would challenge our authority in court, and I must say we welcome that, too.

Mr. Chairman, we fully realize the impact our decision will have throughout the world. Our approval of this experiment would signal to everyone the birth of a new industry. In our State of California, it would generate millions of dollars, creating new jobs and opportunities.

But, as elected officials, I and my colleagues have a responsibility to protect the health and welfare of our citizens. Therefore, before we would approve this experiment, we request the following conditions be part of the regulations pertaining to outdoor testing of this bacteria: That the agencies issuing permits assume financial liability for the project; That local governments please be involved in the approval process; That local governments be given proper notification of any such experiment; That a clear policy and guideline process be established; and above all and most important, we must have a well informed public.

Thank you very much.

Mr. VOLKMER. Thank you very much, Mr. Karas.

Mr. Wong, do you have a statement, too?

Mr. WONG. Yes, I do, Mr. Chairman.

Mr. VOLKMER. Go ahead.

Mr. WONG. Mr. Chairman, Mr. Packard, excuse me. I left California and came out in this cold.

It is apparent that the experimental use permit granted to Advanced Genetic Sciences by the Federal Environmental Protection Agency and the California Department of Food and Agriculture to conduct a field experiment with genetically altered bacteria in Monterey County was processed in a secretive manner that excluded input from local government and from the public. In addition, the exact location of the experiment has not been revealed.

This is Monterey County's first exposure to the subject of experiments with genetically altered bacteria, but it was very obvious that both the Federal and State evaluation process and permit granting process was not in the best interest of the public that we are all supposed to serve.

It is our observation that the Federal and State process is deficient and incomplete in the following areas. I make this statement in a positive manner in that there are others that are going to be coming before and that if we look at this from a positive manner, we may be able to correct our problems.

First, there is no published information available on the application and review process for genetically altered experiments nor small experiments.

Two, there are no published regulations available which regulate experiments involving genetically altered bacteria. Today, you only heard about interim policies. There are no laws or regulations in California, specifically.

Three, there is an apparent lack of aggressive enforcement and of field investigations for violations of regulations of these types of experiments. If there was aggressive field inspections and enforcement, they would have inspected the site and determined it was not remote, and if they had made inspections of the tree experiments, they would have found verification that it was not what they were supposed to be doing. Thus, field inspections and enforcement are needed.

Four, there are no provisions for identifying responsibilities for cleanup should contamination or pollution result from such experimentation. Is the EPA, the State, or the applicant the responsible party to assume the liability?

Five, requirements to actually establish and assess human health risks and environmental effects are lacking.

Six, some departments involved in the permitting process lack personnel qualified to evaluate biotechnology experiments. As an example, in California, we found in the Assembly study that the State Health Department asked for two experts to do this because they didn't have the expertise but it was denied.

Seven, there are no requirements for notifying the public nor local government entities in whose area the experiment will take place.

Finally, although the Environmental Protection Agency recommended that the experiment be located in an isolated and remote area, the site chosen is in a populated region. What is an isolated and remote area? To date, no definition exists.

I may bring to your attention that a letter from Steve Schatzow, director, Office of Pesticide Programs, EPA, to Steve Cole on February 1 states this: "The FIFRA Science Advisory Panel has indicated they would like the testing to be done in an isolated or remote area in California." So, it was not a voluntary issue. There was notification from EPA to the company.

That concludes my presentation. Thank you.

[The prepared statements of Mr. Karas and Mr. Wong follow:]

MONTEREY COUNTY

THE BOARD OF SUPERVISORS

MONTEREY COURTHOUSE - 1200 AGUAJITO ROAD MONTEREY, CALIFORNIA 93940

SAM P. KARAS, CHAIR
SUPERVISOR - DISTRICT 4

HELEN HEMPEL
AIDE TO THE SUPERVISOR

408/ 649-4147

Oral testimony of Sam Karas, Chair, Monterey County Board of Supervisors, presented to the Investigations and Oversight Subcommittee of the House Committee on Science and Technology

Mr. Chairman, Committee Members, and Interested Parties:

I would like to take this opportunity to thank you for allowing us to participate in this vital hearing.

The first outdoor testing of genetically engineered bacteria has focused world-wide attention on Monterey County. The importance of this issue is evidenced by the mass media coverage throughout our nation and Europe. We have received telegrams from members of the West German and European parliaments stating their opposition to the project.

There are various issues involved in allowing this project to go forward. One of the major issues is that in a democracy like ours, citizens have a right to know when a decision is made which can potentially affect their health and safety. This is not to say that the procedures followed by EPA or the State Department of Food and Agriculture were deliberate attempts to keep the experiment shrouded in secrecy. But their actions aroused a great mistrust on the part of elected

officials as well as the public. Failure on their part to notify us of an experiment of such national, if not worldwide significance, is unconscionable. Prior to the issuance of the permits by EPA or the State Department of Food and Agriculture, no public official in the jurisdiction most affected was notified. Never were we included in the approval process by these agencies. If it were not for a petition signed by local concerned citizens, experiments probably would have moved forward without any regard for due process.

It is hard for me to believe that the State Department of Food and Agriculture or the EPA would treat this unusual experiment as a "routine" one. But judging from their actions, this appears to be what occurred. They were aware that by placing the designation of "pesticide" on this project, no environmental impact report would need to be furnished and those agencies would retain regulatory powers rather than allowing local governments to become involved. By their failture to apprise Monterey County of this project, the EPA and the State Department of Food and Agriculture have created a great public mistrust of any future decisions which they may make regarding our county.

It was at this point that we Supervisors felt that the only way to clear the air was to hold a public hearing. So on January 27, 1986, a public hearing was held where testimony

was received from government officials representing EPA, the California State Department of Health Services, Food and Agriculture, as well as from Advanced Genetic Sciences, a number of scientists, the Foundation for Economic Trends and concerned members of the public.

During the hearing, it came as a rude shock to learn from Fred Betz of the EPA that no on-site inspection of the testing area was ever done. The agency was not aware that the site was not located in a rural area, but within ½ mile of a residential area of ten thousand people. And never during the testimony did the EPA state that they would assume any financial liability, which we consider crucial to the issue. As far as we are concerned, the issuance of the permit by the EPA is highly questionable. As a result of the testimony we received at the hearing, it was evident that there was a lack of necessary information on which to base any decision.

We decided to adopt an interim ordinance banning any experiments in our county for forty-five days. By taking this action we allowed ourselves additional time to arrive at solutions to this important problem.

The ordinance prohibits any field experiment in Monterey County using genetically altered bacteria. It is our legal counsel's opinion that the bacteria is of an animal origin, thus it should

be subject to land use regulations. This action gives Monterey County, not the State Department of Food and Agriculture, complete regulatory powers.

To help clarify some points that my occur to you, Mr. Wong and I did visit the Advanced Genetic Sciences Laboratory in Oakland. We were given a tour of the facility and were impressed with the dedication and professionalism of its employees. During our visit we met with key personnel involved in the Frostban project and found them cooperative and willing to answer our concerns. At this meeting we requested more information regarding the testing and were assured the answers would be forwarded to us. We are presently awaiting these answers.

In the meantime we were surprised to learn via a newspaper release in the Washington Post that a test of Frostban had been made on the roof of their headquarters in Oakland during the period of February to June in 1985. No mention had been made to us of such an experiment. It makes us wonder if they have been as candid and frank with us as we thought.

Also, on February 20, Mr. Wong, Director of Environmental Health, Mr. Ralph Kuchler, our County Counsel, and I traveled to Sacramento to discuss this issue. At that meeting, chaired by Assemblyman Sam Farr, were officials from the Departments of Commerce, Health Services, Food and Agriculture, and the Chairman of the Governor's Interagency Task Force on Bio-tech Industry. The meeting was productive, and a great many o' our concerns were addressed.

Financial and health liability, procedure and regulation processes, and a proper method of notification were some of the concerns resolved to the satisfaction of all parties. However, we were advised by the Department of Food and Agriculture that if we invoked a permanent ordinance banning such testing, they would challenge our authority in court.

Mr. Chairman, we fully realize the impact our decision will have throughout the world. Our approval of this experiment would signal to everyone of the birth of a new industry. In our state of California, it would generate millions of dollars, creating new jobs and opportunities.

But, as elected officials, I and my colleagues have a responsibility to protect the health and welfare of our citizens.

Therefore, before we would approve this experiment, we request the following conditions be made part of the regulations pertaining to outdoor testing of this bacteria.

1. That the agencies issuing permits assume financial liability for the project.
2. That local governments be involved in the approval process.
3. That local governments be given proper notification of any such experiment.
4. That a clear policy and guideline process be established.
5. And above all - a well informed public.

Thank you.

MONTEREY COUNTY

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SAM KARAS - BIOGRAPHICAL DATA

Sam Karas was elected Monterey County Supervisor for the 4th District in November, 1984, and was sworn-in and officially assumed office in January, 1985. Sam represents the communities of Seaside, Del Rey Oaks, Sand City, Pacific Grove, approximately half of the city of Monterey, the Monterey Peninsula Country Club area, and the people living in other unincorporated areas contiguous to those areas.

Sam was born and spent his early life in Chicago, Illinois, and is a graduate of Jones Commercial High School in Chicago. While serving in the U. S. Army, he came to Fort Ord in 1943, and remained here after being discharged from the Army. He married a local Monterey resident, Edith James, a former instructor at Monterey Peninsula Community College. They are the parents of three grown daughters, all graduates of Monterey public schools.

Sam Karas's more than 30 years of community service have included offices in local government and education agencies, organization of cultural and special events, and work for various political and humanitarian causes:

1952: Helped organize the Monterey Peninsula Visitor and Convention Bureau (President in 1958)

1957: Helped organize Jazz Festival (Member of Jazz Festival Board for 20 years)

Also: Helped organize Monterey Pop Festival

Past-president, Monterey Folk Festival

Helped organize Monterey Rugby Tournament

Former member:
Urban Renewal Agency of Monterey
Community Theater Board of Directors
Monterey Planning Commission
Executive Committee, N.A.A.C.P. -
Monterey Peninsula Branch
Trustee, Monterey Peninsula Unified
School District for 7 years

1973: Instrumental in securing the referendum that stopped development at Tarpey Flats

1981: Led opposition to Monterey II by placing an initiative on the ballot which passed, forcing any new plan for Tarpey Flats and Monterra to be voted upon by all the citizens of Monterey.

Sam serves as Chair of the Monterey County Board of Supervisors for 1986. He serves on the Monterey Bay Air Pollution Control District, L.A.F.C.O., Mental Health Advisory Board, Monterey County Transportation Commission (alternate), and the Monterey County Cultural Council. He also is a member of the Health Care and the Legislative subcommittees representing the Monterey County Board of Supervisors.

Oral Statement of Walter Wong, Monterey County Director of Environmental Health, presented to the Investigations and Oversight Subcommittee of the House Committee on Science and Technology.

It is apparent that the experimental use permit granted to Advance Genetic Sciences by the Federal Environmental Protection Agency and the California Department of Food and Agriculture, to conduct a field experiment with genetically altered bacteria in Monterey County, was processed in a secretive manner that excluded input from local government and from the public. In addition, the exact location of the experiment was not and has not been revealed.

This was Monterey County's first exposure to the subject of experiments with genetically altered bacteria, but it was very obvious that both the federal and state evaluation process and permit granting process was not in the best interest of the public that we are all supposed to serve.

It is our observation that the federal and state process is deficient and incomplete in the following areas:

1. There is no published information available on the application and review process.

2. There are no published regulations available which regulate exppriments involving genetically altered bacteria.

3. There is an apparent lack of aggressive enforcement and of field investigations for violations of regulations in these types of experiments.

4. There are no provisions for identifying responsibilities for cleanup, should contamination or pollution result from such experimentation. Is the EPA, the state, or the applicant the responsible party to assume such liability?

5. Requirements to assess human health risks and environmental effects are lacking.

6. Some departments involved in the permitting process lack personnel qualified to evaluate biotechnological experiments. An example is the State of California's Department of Health Services.

7. There are no requirements for notifying the public nor local government entities in whose area the experiment will take place.

8. Although the Environmental Protection Agency recommended that the experiment be located in an isolated and remote area, the site chosen is in a populated region. What is an isolated and remote area? To date, no definition exists.

Mr. VOLKMER. The problem with that is, Mr. Wong, as I understand it from EPA, they have no authority to require them. In other words, EPA can't pick the site. It is up to the company to pick the site. EPA basically just has to concern itself with the safety and health aspects of the site.

I agree with you that they should have checked this out first since this is the first ever of anything like this being done and all that, as Mr. Panetta has pointed out, all that should have been done. The public reaction may have been a lot different if everybody was informed and all these things were covered beforehand. I am sure, I hope, that they at least have learned from this because we are going to have others as time goes on.

Mr. Karas, I would like to ask you when does your 45 days run out?

Mr. KARAS. March 28.

Mr. VOLKMER. March 28. Let's hope that EPA will be completed with their investigation by March 24.

Mr. KARAS. I hope so.

Mr. VOLKMER. I am sure you are going to be interested in that just like we will.

Mr. KARAS. Yes.

Mr. VOLKMER. I don't have any further questions for the panel. I do appreciate the opportunity.

Maybe I can, and I am not asking if you would make a decision at this time, but is there any possibility or likelihood that in the event that after the investigation comes out that everything is OK after all—let's assume that the experiments that were done on the rooftop turn out to be valid, that the methodology and everything does prove out, and that there is no pathogenicity to these strains as far as any scientific evidence concerned. Then, and I am not saying at this site, is there a possibility that if they would pick a site, as Leon has pointed out, there are others that are more remote where strawberries can be grown, knowing what you know now about everything and having visited those people, would it be possible that they could have a test in Monterey County?

Go ahead. Answer it in your own words. I am not trying to put you on the spot.

Mr. KARAS. My wife is the only one who can do that, but I just wanted to answer it in this way. On January 7 when we first heard about it, we could have killed the whole project right there at the Board of Supervisors meeting. I want you to understand that we are neutral. We realize the significance of what is before us, we do. We had a public hearing to allow AGS to present their case. It was not for us to attack AGS. It was to allow them their case.

At all times, we have tried to be cooperative with them. To answer your question, there is a great problem involved and the problem is this. It is mistrust.

And I will tell you where the problem is now coming from. We would like to see it in another area, but now they are going to other people for another site and the other people whom now they are going to for a site have now become involved because they have a mistrust of AGS, and that is the problem that faces them.

To answer your question, I would wait until March 28 to say yes or no, but if we could find a site, a rural site, it would go a long way to maybe making a favorable decision. Let's put it that way.

Mr. VOLKMER. There is some public perception out there that because of what has occurred, there is other mistrust. The question is how do you eradicate that? How do you break that down?

Mr. KARAS. I don't want to keep the hearing. Let me just say one more thing. When we were in Sacramento, we met with these different departments. They offered to come down and meet with the opposition for 3 hours and try to compromise the problem. I must tell you I told them don't come into Monterey County, and I don't mean in a bad way, but there is such a great mistrust of government agencies right now in our county that they are going to have to go a long way to restore the faith in it.

Mr. PANETTA. Mr. Chairman, if I might, it was just a great example of how, once you make some serious mistakes, it is difficult to recoup. Had they taken the time, I think, to sit down with myself and with the county and present exactly what was to be involved, even prior to actually getting the permit, for that matter, and laid the groundwork with the Board of Supervisors and with the other members of the Board of Supervisors and with the Health Department so that everyone was aware of it rather than having it suddenly hit the papers and then finding out that that was the case, that really began the undermining process.

As a consequence of that, there was a fear of what are they hiding and what is involved here. What is the problem? And the public now shares that fear.

Add to that the situation that happened in Oakland on top of this, you can sense why this has become such a serious problem there in terms of the community because they are concerned are they getting the straight scoop. That is the problem.

Mr. VOLKMER. You mean with the rooftop experiment.

Mr. PANETTA. Sure.

Mr. VOLKMER. Right. I can understand that. I think everybody can understand it. They have only hurt themselves.

I have no further questions.

The gentleman from California?

Mr. PACKARD. I think we share some of the same concerns. I come out of local government, and I recognize that we struggle enough with dealing with our people with an open policy that this kind of a circumstance simply undermines that ability.

I do want to question, however, your recommendation that local governments be involved in the approval process. Under what arrangement and how do you suggest, Mr. Karas, that local government does have a part of the approval process in these kinds of experimental projects?

Mr. KARAS. Well, of course, the question comes back, then, is it a land use plan? We hold the theory that the bacteria itself should come under a land use plan which gives us approval process. That is what we are really concerned with.

And I think the other thing is we are talking about not an ordinary experiment that is taking place in the world today. We are talking about something unique. And that is why I am saying two things; one, the notification and also the approval process, but we

consider land use. That is why we believe we should be involved in the approval process.

Mr. PACKARD. In this specific circumstance, we are looking at a microbe that I suppose could be—although I understand the interpretation has already been made by the agencies involved—that this is not an animal, that it does fit into the pesticide area. But I would have to assume that for the same reasons, then, you would be interested in having approval power over pesticide testing.

Mr. KARAS. I would say—that is a tough one to answer, because in one respect, I think some of the pesticides today should come under the approval of the county board of supervisors. You are from California; you know the problems we have back there.

Mr. PACKARD. I am very interested because I have almost an agricultural environment similar to yours.

Mr. KARAS. Exactly.

Mr. PACKARD. Frankly, your county and my county could probably benefit most from this kind of experimentation in terms of the quality and type of agriculture that takes place in our area. We could probably find, although you maybe more than us simply because we don't have that much frost in our area, but nevertheless certainly it could benefit the whole agricultural area of your part of California and mine, too.

But I am also concerned about the liability aspect, because I see a little bit of a dichotomy in your first two requests.

Mr. KARAS. Yes, Congressman Packard, can I answer that for you? I meant to say that we haven't resolved the financial liability part. When I was sitting over there with AGS, they will assume financial liability of the project. I hope that answers your question.

Mr. PACKARD. Well, it may in theory, but in real practice, the deep pocket theory—which we live in a crisis situation right now on that issue—and I know who is going to be responsible for the liability. It is not going to be AGS ultimately, especially when I look at their cash flow. It is going to be the County of Monterey, and it is going to be the cities that make the approvals, because I came out of city government, and I know where the deep pockets ultimately go. With the joint and several and strict liability laws that are now in place and that we are struggling with, you would assume some significant liability if you assumed part of the approval process.

I simply want you to be aware, and I am sure you are, that you can't take approval responsibilities and yet push the liability responsibilities off onto someone else. It doesn't work in the courts that way.

Mr. KARAS. Right.

Mr. PACKARD. But be that as it may, I don't disagree that certainly there ought to be information for the people. Local involvement ought to be there. How to do that is going to be difficult because, frankly, these kinds of experiments, and I think rightfully so come under federal and state jurisdiction. To bring that down to the local level, I think, would fragment the approval process to the point that there would be little continuity and regulation that could keep it all under the same umbrella. But that is still a question that I think EPA and other state agencies would have to evaluate.

Let me just ask, under what circumstances would you feel that this experiment and testing would be appropriate in your county?

Mr. KARAS. If it is 100 percent safe. I must say, I know it is a hard thing to say, but——

Mr. PACKARD. I think we could all agree there.

Mr. KARAS. Right. Again, I want to tell you, we were up in Sacramento, and the deputy director of the Department of Food and Agriculture said to me, well, it is 99 percent safe, and I said swell, but you tell that 1 percent over there that they have nothing to worry about.

Mr. PACKARD. Then, let me ask you a follow-up on that. Where would it be 100 percent safe outside of Monterey County?

Mr. KARAS. Do you want me to really answer that?

Mr. PACKARD. It isn't, is it?

Mr. KARAS. Belgium. [Laughter.]

Mr. PACKARD. There is always the idea of doing it in somebody else's back yard but not in mine, and I appreciate that. It is a dilemma that we struggle with.

Mr. KARAS. Really, it is.

Mr. PACKARD. I think we can all agree we would like to see this kind of experimental activity take place. It is good for the country, it is good for the industry, it is good for our areas, but don't do it in my area and don't put experimental oil wells off my coastline, Leon. We come from common ground in that area. It is easy for us to feel that way, but a company——

Then, as I looked at the little plot map, I have to assume that the company itself, AGS, chose the site. Again, I think the chairman made it clear that the responsibility lies with the companies that do the experiments to choose the sites and then go through the approval process to see if that site adequately addresses the safety features.

But I have to assume that the reason they chose it is because they own the property. It is pretty hard to do this kind of experiment on somebody else's property. For that reason, I am sure that is why this site was selected even though it was perhaps not as isolated as what some were led to believe.

I don't have any real questions. I sympathize with the local environment. I would have the same concerns if I were on the Board of Supervisors in Monterey County, and I hope you recognize that the process has pretty well been established as to how these kinds of things are approved. If the process needs to be changed, then we ought to go about doing it, and part of the purpose of this hearing is to see if that adequately addresses the safety features and the other features that these kinds of experimental projects involve.

I think that is what we want to do, is to make certain that they are as safe as it can be done. No experiment is 100 percent safe.

Mr. KARAS. Right.

Mr. PACKARD. Thank you, Mr. Chairman.

Mr. VOLKMER. Thank you very much. I appreciate the panel, Leon, and your testimony. We appreciate it.

Mr. KARAS. Mr. Chairman, just one thing. May I thank your staff for being so kind to us. I really mean that very sincerely. Thank you very much.

Mr. VOLKMER. Well, I appreciate your being here and giving us an idea of the concerns that face that area and what happens when it is done in the method that it was done. Now, I will tell you why, Mr. Karas, because probably the next field test that is going to take place in the United States will be in my district.

Mr. KARAS. Oh, really?

Mr. VOLKMER. Yes; I thought you ought to know that, and I hope that this kind of thing doesn't happen there, because I feel very strongly in the field of biotechnology and where we are going. I feel very strongly that we need to pursue this area that, like Leon said, holds a great deal of promise for the future.

Mr. KARAS. I think we all agree on that.

Mr. VOLKMER. And I hope that we will be able to work it out.

Mr. KARAS. Thank you. By the way, my wife will not serve strawberries.

Mr. VOLKMER. Thank you very much.

Our final witness is Mr. Glenn Church from ALERT in Monterey, CA.

Mr. Church, will you raise your right hand? Do you swear to tell the truth, the whole truth, and nothing but the truth, so help you God?

Mr. CHURCH. Yes, I do.

Mr. VOLKMER. All right. Thank you. Your prepared statement will be made a part of the record at this point in the record in full. You may either review the statement or summarize, however you so desire.

STATEMENT OF GLENN CHURCH, ALERT, MONTEREY, CA

Mr. CHURCH. Good afternoon.

First, I would like to express my gratitude to be here today.

I would prefer to believe in this new technology than to doubt it. I would like to believe the promises of the biotechnology industry of greater harvests and a cleaner environment. Unfortunately, the promises have neglected the potential problems, and I find it hard to trust today, after 2 months of encountering the negligence of Advanced Genetic Sciences and the regulatory void of the Environmental Protection Agency.

Today, I have only questions and doubts. Today, we stand on the threshold of the future. Once the door is opened to this new technology, it will not so easily be shut again. This is a technology that will be with us until the end of human history. I only hope that the door is opened with the caution it deserves.

The people in Monterey County understand that this experiment is considered a low risk test by the experts. But low risk means there is still a risk. If something does go wrong, it can have potentially catastrophic effects on some of the richest agricultural land in the Nation.

With that in mind, it seems inappropriate to grant permits before a science of risk assessment for genetically altered organisms is developed. How definitive can guarantees be when the science to give us those guarantees is still forming?

There is concern about the long-term effect of these bacteria on the environment and agriculture in our county. We believe there

needs to be more testing, testing that will be monitored closely by Government agencies. This issue must be addressed rationally and calmly, not with the recklessness seen so far by AGS and EPA.

It is disturbing to realize that without the concern of a local community, the ice-minus bacteria experiment would probably now be in its final stages of completion without any of the new developments now publicly known. Somewhere the process has broken down.

I am not alone in expressing the fears that the regulatory process is more attuned to promoting the biotechnology industry than in protecting the public. How else can it be explained that EPA never bothered to visit the proposed test site in Monterey County before granting the permit? EPA's information to assess the suitability of the site was supplied by AGS in a general description. How can a neutral decision be arrived at under these conditions?

There is dismay that the EPA allows the test site of this experiment to be shrouded in secrecy. The public still does not know the exact location of this experiment despite repeated requests to EPA and AGS, by the way. A company's privacy has been placed above a community's right to know. Is it proper for the EPA to serve the company in preference to the community?

The EPA recommended that the ice-minus experiment take place in a remote area. But the test area is home to 10,000 people, and a rural population of 20,000 live around it. Only 10 miles away is a city of nearly 100,000. By no stretch of the imagination can this be considered remote. Why was this site allowed to be selected by AGS?

The regulatory process seems far behind in handling this special problem of this industry. What other reasons can explain application of chemical pesticide laws to organisms that can multiply, migrate, and mutate, traits not found in chemicals? These organisms are not like chemicals that have half-lives. Once placed into the environment, they are out there forever.

AGS has led the people of Monterey County to believe that the experiment there was to be the first deliberate release in the world. Now, we find that these bacteria were released as early as last year.

AGS has stained its credibility with the people in Monterey County. AGS has not been open to us about the test site and now about the release. There is little faith to be placed in a company that has violated the public trust.

There is the possibility that the Federal Government may not prosecute a violation of Federal law already acknowledged by the EPA. Here is the first deliberate release of genetically altered bacteria in the world, and it is being acted on slower than a parking violation. This violation deserves more than a simple wrist slapping.

What happened at the AGS laboratories was an historic event, but in the process, they showed disregard for the public, the environment, and Federal law. If AGS is allowed to go ahead with the first legal deliberate release after flaunting the law, what precedent will this set for the industry?

The public is far more sophisticated today than ever. The image of the Three Mile Islands, Love Canals, and Bhopals have shown

the world that new technologies bring risks as well as advancements. The sloppy work, negligence, and arrogance of AGS, and the inadequate regulation of the EPA have not reassured the public trust. Rather, the stage is set for a disaster waiting to happen, if not in California, then somewhere else.

The incompetence that the EPA shows when it did not know that outdoor trees were experimented on and windows in supposedly contained greenhouses were opened. I hope this is not happening in laboratories across the country.

Why does this experiment and others have to be rushed into outdoor testing? Why cannot we wait until these controversies are settled? It may be perfectly acceptable to rush a product to market when it is a soft drink, but when it is a new life form, it requires a greater degree of responsibility.

What can you do to assure us that this experiment will not go forward without our will?

Thank you.

[The prepared statement of Mr. Church follows:]

STATEMENT OF GLENN CHURCH

PRESIDENT, CONCERNED CITIZENS OF NORTH MONTEREY COUNTY,

470 HIDDEN VALLEY ROAD

WATSONVILLE, CA 95076

(408) 663-3804

BEFORE THE

COMMITTEE ON SCIENCE AND TECHNOLOGY

SUBCOMMITTEE ON INVESTIGATION AND OVERSIGHT

MARCH 4, 1986

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guarantees is still forming?

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What can you do to assure us that this experiment will not be rushed forward against our will?

Mr. VOLKMER. Thank you very much, Mr. Church.

I guess I don't have very many questions, but it appears to me that you have not just an AGS but you have a basic suspicion of all biotechnology organisms or organisms developed through biotechnology, gene splicing, DNA, and so forth.

Mr. CHURCH. No, I believe that biotechnology has brought some great advancements in medicine, for example, in the development of insulin. I think it has a great deal of advancements it can make there. I think that biotechnology is something that holds a great promise, and I think it is something of the future.

But what I am afraid of is right now this regulatory process and perhaps the research that is being done is not adequate. That is what my concern is.

Mr. VOLKMER. Well, in the first place, I think the hearings we held in December, I think it came out, and I firmly believe that we need additional research into the areas of being able to properly test the bacteria or whatever is being developed in the field. The question is whether that is getting ahead of the methodology in testing. I won't argue with that and that we need to.

The other thing, you agree then that the whole area holds a great deal of promise, even cleaning up our hazardous waste sites possibly even through enzyme production, and so forth, that could break down some of that. So, from an agriculture area, I see a great potential in the use of this.

Mr. CHURCH. I agree with you. I am a farmer, too, by the way, and I do think that it does hold a lot of promise. I just think there are some real questions. I think we have heard that today from EPA and AGS just about what this company has done and about the regulatory process.

Mr. VOLKMER. Well, I think what this company, AGS, has done has probably set us back a little bit in public relations. I won't argue that at all. I just don't want to see what happened stop altogether in its tracks the future in this area, though, either. You understand what I am saying.

Mr. CHURCH. Yes; I understand what you are saying.

Mr. VOLKMER. And Government can, and I think Government has—you are right—a responsibility in the area to make sure that once something is released that it is safe. There is no question about it, but as the gentleman from California has pointed out, Government can at times be overburdensome, too, to a point where we just stifle growth. Do you agree with that?

Mr. CHURCH. I believe there are times perhaps it can be overburdensome. I think the decision perhaps to be looked at here is what is more dangerous, underburdensome or overburdensome?

Mr. VOLKMER. Right, we need to protect the environment, is what you are saying.

Mr. CHURCH. I think environment and people, too. I think there are a lot of concerns to be looked at here. I think there are a lot of things that make this ice-minus bacteria look rather benign. I am afraid the EPA may not be at this point ready to really regulate a lot of things properly. I hope that this will spur them on.

Mr. VOLKMER. I wish to let you know that we will be monitoring their investigation and we will probably hold hearings after their

investigation is complete so we can air it all in public. I think it needs to be. I think that has been part of the problem with AGS.

I have no further questions.

The gentleman from California.

Mr. PACKARD. I really don't wish to prolong the hearing any longer; it has been a long hearing for all of us involved. I would like to probably simply inject as a result of your testimony one part where it says I am not alone in expressing the fears that the regulatory process is more attuned to promoting the biotechnology industry than in protecting the public.

I just simply don't believe that is true. I think just the opposite is generally perceived that all those who get involved in scientific research find that the regulations become an extremely burdensome problem for them to deal with, that we recognize that they have to deal with that regulation. I don't believe that our regulation is geared to promote any biotechnology industry or company. On the contrary, I think they are the ones who most bitterly complain about the regulations, but be that as it may, the regulation is there.

I don't see us, however, shifting our emphasis on regulation a great deal either from this hearing or from past experience.

I think there are some—and I will just conclude with this comment, Mr. Chairman as I have really no questions—I think there are some in our society who believe that any altered or genetically manipulated microbes are inherently dangerous and, therefore, ought to be shunned like the plague and that any exposure to genetically engineered bacteria or microbes, if it were released to the public or to the environment, would be like releasing a plague in the world.

I think that is a misconception that is hindering the progress of this whole industry which to me holds one of the great and bright lights of the future for America and for the world if it is handled properly. I think we ought to do all we can to try to suppress this concept among some that we are playing with dynamite, we are playing with that which will destroy us and we ought to push it out of our communities, any experimentation in this area.

I think that would be a mistake. Frankly, the scientists involved in this process are the most vulnerable, as most scientists have always been. They have the greatest exposure. They are working with these microbes. They are doing the genetic engineering of it. They obviously receive the greatest exposure, yet they are the most profound proponents of moving forward with the work they are doing.

I simply feel that we need to be cautious on the other side as well as the protection of the environment and the health and safety of our people, and, believe me, I am in favor of that. But I think we ought to also have some caution on the other side of the coin that we don't drive this emerging industry and technology into an attitude where the public says it is another plague, let's avoid it.

That is simply all I have to say. I think that we have got at something here that is going to require some balance in our regulations and balance in our attitudes, and that I guess is one of the risks. We were talking about that the other morning in one of our

science policy committee hearings; what kind of problems do we run into when there is total information available to the public, and I am certainly in favor of that as much as possible, but sometimes a portion of the public uses that information to create a stumbling block for the science.

The scientists, therefore, have almost an inherent inhibition of giving out information because they are constantly being confronted with inaccurate throwbacks of that information that places significant hurdles that they cannot cross and ultimately drive them out of the scientific research field into the private sector because the money and the problems that they have to face in experimenting simply don't exist out there. That sometimes is a dilemma that our scientists are struggling with now. Frankly, I don't know that there is a good answer.

Mr. CHURCH. Just a short comment to what you said in questioning my statement about regulations promoting or not the regulations but the Government promoting the industry, specifically what I was talking about. There was a bill passed in the California Assembly a couple years ago that was talking about the promotion of the industry. That was really before regulations had been adopted. I do not feel also that the EPA had really taken the chance to go and evaluate the test site also, which I consider to be something that was protecting the public.

Mr. PACKARD. I can't address legislation in the State of California, obviously, from this vantage point, but I certainly do appreciate your testimony and certainly understand your concern, and we have some work to do.

Thank you, Mr. Chairman.

Mr. VOLKMER. I would just like to say in closing that we have to remember, too, that the whole Federal regulatory process has been evolving, and I think it is becoming more definitive as time goes on. We have been watching it very closely, and we will continue to do so to make sure that it operates properly.

From this hearing, I would just like to say, too, it clearly appears to me that the problems that AGS is now having were basically of their own making. They have no one to blame, in my opinion, but themselves. I don't think it would be fair for them in any way to blame either the people of Monterey, CA, or the Federal EPA or anybody else. I just don't think that they really concerned themselves close enough to what they should be doing.

I would say, too, that it is important to keep a close watch and we are going to do so on the biotechnology industry. Most companies have been open about the nature of their tests, the locations of those tests, and here we have an instance in which a test has been conducted in a noncontained area under uncontrolled conditions in a way that casts doubts now on the validity of the data they supplied to EPA, at least questionable.

In addition, EPA has relied on this suspect data in approving the first field test of a genetically engineered organism. This is not the way such a momentous event should occur.

I am further troubled by the location of the field test. A residential site near crops, plants, is not the proper place to test this bacteria. It is inexcusable that local citizens and Government agencies

were not told of the proposed test site in advance of approval of the site.

The data and the photograph I have obtained conflict with the data reported to EPA by AGS. I will expect a full investigation of this conflict by EPA. I further expect that EPA will take disciplinary action regarding the violations of the interim policy and the possible omission of data to a degree commensurate with the importance we all attach to the release into the environment of genetically engineered organisms.

Thank you, Mr. Church. We appreciate your coming all the way from California. We thank all the witnesses today.

That will conclude the hearing.

[Whereupon, the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIX 1

Chronology of Events

NIH RAC submission by AGS	March 22, 1984
NIH RAC hearing to review AGS submission	June 1, 1984
RAC Workgroup further review of AGS submission	June 84-October 84
Issuance of EPA Interim Policy on Small Scale Field Testing of Microbial Pesticides	October 17, 1984
Letter from NIH RAC to AGS stating that the RAC moved to send the application to the NIH Director for approval, although the RAC Workgroup requested more data and additional measures to monitor the test.	October 18, 1984
AGS notification of EPA of proposed field testing as required by EPA interim policy	November 5, 1984
Letter from AGS to the RAC providing additional information	November 15, 1984
Notification reviewed by HED, SAP subpanel, Intra-Agency Workgroup on Biotechnology	Nov. 84- Jan. 85
Additional data sent to EPA by AGS	January 10, 1985
SAP Subpanel meeting	January 22, 1985
HED position on initial AGS notification issued	January 30, 1985
Letter from EPA to AGS requiring EUP application and additional information	February 1, 1985

Additional research conducted by AGS to provide requested information	Feb. 85 - July 85
AGS EUP application and additional data sent to EPA	July 2, 1985
Federal Register notice published announcing receipt of EUP application; 30-day comment period provided.	August 21, 1985
HED preliminary position on EUP application issued.	August 27, 1985
USDA, FDA, NIH, SAP, subpanel, and Intra-Agency Workgroup on Biotechnology review of EUP materials	Sept. - Oct. 1985
HED response to comments from Intra-Agency Workgroup on Biotechnology, SAP subpanel, and the public	November 5, 1985
HED final position memorandum on AGS EUP application	November 5, 1985
EPA decision memorandum granting AGS EUPs	November 14, 1985

Appendix 2

Table 1f. Inoculation methods for tests of pathogenicity to plants.

Inoculation method[a]	Inoculum dose CFU/ml	Plant[b]	Reference
Branch injection	10^7	cherry, peach apricot, plum almond, pear	13, 16
Green fruit injection	10^8	pear	58
Internode injection	10^8, 10^6	oleander	83
Stem injection	10^5	potato[c]	21
Leaf swab	10^8	tomato[c]	74
Leaf infiltration	10^5	soybean[c]	35
Pod injection	10^8	snap bean	47

[a] Plants were incubated on a greenhouse bench and/or under moist conditions at 21 ± 5 C as recommended by reference publication.

[b] Latin names and cultivars given in Table 1g.

[c] Method recommended for plant named. Method also used for the following plants: tobacco, tomato, potato, oat, wheat, barley, strawberry, bean, alfalfa, corn, cucumber, lettuce, beet, rape, cotton, and all weed species.

Table 1g.- Reactions of plants inoculated with wild-type INA$^+$ and INA$^-$ deletion mutant strains of Pseudomonas syringae and P. fluorescens biotype A.[1]

Cultivated Plants	S203 (+)	NGP36 (−)	MS1650 (+)	GJP178 (−)	Positive Control[2]
Lycopersicon esculentum (Mill) cv. 'VF145B7879'	-	-	-	-	+
Solanum tuberosum (L.) cv. 'Russet Burbank'	-	-	-	-	
Nicotiana tabacum (L.) cv. 'Glurk'	-	-	-	-	
Avena sativa (L.) cv. 'Cayuse'	-	-	-	-	
Triticum aestivum (L.) cv. 'Probrand 771'	-	-	-	-	
Hordeum vulgare (L.) cv. 'Himalaya'	-	-	-	-	
Medicago sativa (L.) cv. 'Moapa 69'	-	-	-	-	
Fragaria X Ananassa (Duch) cv. 'Douglas'	-	-	-	-	
Phaseolus vulgaris (L.) cvs. 'Topcrop' & 'Eagle'	-	-	-	-	+
Glycine max (L.) Merrill cv. 'Cumberland'	-	-	-	-	+
Zea mays (L.) cv. 'PK20'	-	-	-	-	
Cucumis sativus (L.) cv. 'Burpee hybrid'	-	-	-	-	
Lactuca sativa (L.) cv. 'Arctic'	-	-	-	-	
Beta vulgaris (L.) cv. 'SS-E1'	-	-	-	-	
Brassica napus (L.) cv. 'Emil'	-	-	-	-	
Gossypium hirsutum (L.) cv. 'Pima'	-	-	-	-	
Nerium oleander (L.) cv. 'Sister Agnes'	-	-	-	-	+
Prunus dulcis (Mill) Webb cv. 'Non Pareil' & 'Mission'	-	-	-	-	
Prunus avium (L.) cv. 'Black Tartarian' & 'Bing'	-	-	-	-	+
Pyrus communis (L.) cv. 'Bartlett'	-	-	-	-	+
Malus sylvestris (Mill) cv. 'Yellow Delicious'	-	-	-	-	+
Prunus armeniaca (L.) cv. 'Blenheim'	-	-	-	-	
Prunus persica (L.) Batsch. cv. 'Late Elberta'	-	-	-	-	
Prunus salicina (Lindl.) cv. 'Late Santa Rosa'	-	-	-	-	
Weeds					
Chenopodium album (L.)	-	-	-	-	
Portulaca oleracea (L.)	-	-	-	-	
Melilotus officinalis (L.)	-	-	-	-	
Convolvulus arvensis (L.)	-	-	-	-	
Poa annua (L.)	-	-	-	-	
Solanum nigrum (L.)	-	-	-	-	

[1] Methods given in Table 1F.

[2] Positive controls were pathogenic strains of Pseudomonas syringae.

APPENDIX 4

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MARCH 4, 1986

DATA REGARDING EFFECT OF ICE-MINUS BACTERIA ON TREES

One of the pathogenicity tests which was particularly interesting was conducted with four commercial isolates plus various positive and negative controls. The treatments were as follows:

1.	S-203	Pseudomonas syringae	ice nucleation positive
2.	RGP-36	" "	ice nucleation negative (Frostban?)
3.	GJP-17B	" fluorescens	ice nucleation negative
4.	MS-1650	" fluorescens	ice nucleation positive
5.	NCPPB2787	" syringae	pathovar morsprunorum (+ control)
6.	0.01 M PO4 buffer		(- control)
7.	PSS27	Pseudomonas syringae pv. syringae	(+ control)
8.	PSS40	" " "	(+ control)

The isolates of primary interest to AGS were RGP-36 and GJP-17B. The latter was a P. fluorescens which was expected to be safer in the environment and easier to get a permit for testing. RGP-36 was a candidate for the Frostban market which was developed independently of Dr. Lindow by AGS. I did not take part in the testing of Lindow's ice nucleation negative P. syringae. I injected RGP-36 into twigs, buds, and leaf scars of the following types of trees:

Texas Mission almond	Blenheim apricot
Nonpareil almond	Bing cherry
Neplus almond	Black Tartarian cherry
Elberta peach	Montmorency cherry
Santa Rosa plum	Yellow Delicious apple
Bartlett pear	

For most types of trees 4 injections were made on each of 4 branches. This was done on one-year wood in the spring of 1985. The trees were 5 to 10 feet tall, growing in 5 to 8 gallon containers on the roof of the AGS building. (Near the greenhouses shown on page 5 of the 1984 AGS Annual Report.)

The experiment was conceived and designed initially by Dr. Julianne Lindemann and Dr. Trevor Suslow. Their previous experience with conducting pathogenicity tests on deciduous trees was quite limited. I believe Dr. Lindow at UC Berkeley may have been consulted because he was usually consulted regarding any major project in the Biocontrol Group.

One early problem with the trees was that many of them failed to leaf out prior to the test. Mishandling during and after shipment from the nursery was the suspected cause of this. As a result we had fewer Texas Mission almond trees than planned. The number of injected branches had to be cut to 3 per treatment instead of 4 per treatment for this variety of almond. Some of the branches had wounds which closely resembled small cankers (1 to 2 cm long) from possible microbial infections. Dr. Lindemann did not believe this was serious enough to warrant discarding the trees and instructed me to inject branches which had no previous wounds. One of the 12 injections with RGP-36 developed a large 3 to 4 cm long canker approximately 25 days after being injected.

Prior to this I had reported to Dr. Lindemann that several of the injection sites for RGP-36 on Elberta peach were slow to heal. There was also a previously unnoticed small canker near the areas injected on one Bing cherry tree. This first group of trees received 7 injections per branch of treatments #1 through #6. Our first concern had been to make sure the positive control produced symptoms of infection, because we had read and heard that this might be difficult. Eventually the consensus became that we might have difficulty controlling conditions so that the commercial isolates would produce no symptoms while, at the same time, the pathogenic positive controls multiplied and produced symptoms. Eventually I was instructed to reduce the inoculum density from 10 e7 CFU/ml to 10 e5 CFU/ml for

all treatments in all future tree injections. One other incident, which I thought was an accident at the time, was that a labeled branch injected with MS 1650 was neatly pruned off one of the Elberta peach trees. This occurred after I had noted the obvious flow of sap from 1 of 7 injection sites on this branch.

On several occasions I suggested attempting to isolate injected bacteria from the open wounds and a random sample of the healed over injection sites. Suslow and Lindemann expressed an interest in this idea but seemed to give it low priority. There were several other projects which they wanted me to work on which were monitored more closely and given higher priority. I made one attempt to isolate RGP-36 from the Texas Mission almond canker but was unable to obtain any fluorescent colonies.

Pathogenic pseudomonads are known to be difficult to isolate from woody plants, even when cankers and infection symptoms are quite obvious. Some researchers have reported success only during early spring prior to full expansion of new leaves. Hot, dry weather kills pseudomonads, changes the host's nutritional status, and is suspected to bring on a hypobiotic resting stage of some bacteria. Reviving hypobiotic bacteria is thought to be difficult - especially if they are in non-sterile host tissues. Non-pathogenic bacteria can usually outgrow pathogens on common culture media.

The cause of the injection-site canker on the Texas Mission almond remains a mystery. I had planned to repeat the test in the autumn of 1985 when the roof-top environmental conditions became a little more conducive for Pseudomonas infection. Some of the previous inoculations, conducted in late spring, did not reasonably simulate conditions associated with Pseudomonas infections. The pathogenic positive controls produced cankers smaller than 1 cm in length. Many branches injected with positive controls failed to develop symptoms and even appeared to heal more quickly than some of the commercial isolates. The roof site was hot and breezy. The potted trees frequently required two hand waterings per day. The microclimate of the branches and leaves was considerably different than what would be expected in the producing orchards of California - especially during the spring frost season.

One of the projects which drew me away from completing Koch's Postulates on the tree inoculations involved greenhouse plants. The general lack of uniform, typical symptoms on tree branches injected with positive controls caused me to plan some changes in environmental conditions when possible. I reviewed the methods described in Fahy and Persley's Plant Bacterial Diseases (Academic Press Australia, 1983). For greenhouse tests of Pseudomonas pathogenicity they usually suggested using intermittent water misting, high humidity, and a temperature range of 20 to 25 degrees Centigrade.

• • •

Eventually I began to feel very uneasy about not following standard procedures for pathogenicity testing. I was under continuous pressure to use low levels of inoculum, growth rooms that were hot and dry, and to skip over attempts to complete Koch's postulates when unusual symptoms developed. I believe that I was gradually being "set up" to take the flak if the ADS bacteria caused environmental problems. Everyone seemed sure that there would not be any serious, detectable problem. Yet, nobody had the confidence to really put the bacteria to the test in the greenhouse, growthchamber, etc.

APPENDIX 5

DON FUQUA, Florida CHAIRMAN

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General Counsel
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U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE AND TECHNOLOGY
SUITE 2321 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-6371

March 7, 1986

CONFIDENTIAL

Mr. Lee Thomas, Administrator
Environmental Protection Agency
WT-1200; A-100
401 M St., SW
Washington, DC 20460

Dear Mr. Thomas:

In November 1985, EPA granted Advanced Genetic Sciences, Inc. (AGS) of Oakland, California an Experimental Use Permit (EUP) to field test a genetically-engineered strain of bacteria which prevents the formation of ice on plants at certain temperatures. The Science and Technology Committee's Subcommittee on Investigations and Oversight, which I chair, held a hearing in December 1985 on the issue of deliberate release of genetically-engineered organisms. At the hearing, Mr. John Moore from EPA testified that the agency granted the EUP based on data submitted by AGS that showed that the genetically-engineered bacteria was not pathogenic to trees or plants. This data was based on experiments conducted by AGS at the request of the EPA in a period from February 1985 through July 1985.

On March 4, 1986, the Subcommittee on Investigations and Oversight held a hearing to investigate allegations that AGS had conducted uncontained experiments with a genetically-engineered bacteria on the roof of its office building in California. In preparation for the hearing, the Subcommittee staff was provided with a confidential document that indicated that data submitted by AGS to EPA regarding the pathogenicity of the ice-minus bacteria may have been misleading or incomplete. If the allegations contained in the document obtained by the Subcommittee are true, it will raise questions concerning the veracity of the remaining data submitted to EPA by AGS and could invalidate EPA's conclusions based on that data.

The Subcommittee is willing to provide a copy of the document (with personal references deleted from the document) to the Environmental Protection Agency under the following conditions; to which we ask EPA's agreement in writing:

The document should not be released to anyone except those in EPA with a need to know who are currently involved in the investigation. It should be kept confidential and in a secure location. It is understood, however, that EPA may, at a future date, release the document should it become necessary in any judicial or administrative proceeding in which the document would ordinarily be relevant and discoverable.

The Subcommittee is concerned that the following points warrant examination by the agency:

1. Were the pathogenicity tests referred to on p. 2 paragraph 3 (of the document) supposed to be conducted on dormant trees or were they to have been done on trees which had leaves?

2. Was the canker reported on p. 2, paragraph 3, cultured to determine whether or not the ice-minus bacteria caused the canker?

3. When wounds were discovered on the trees prior to their use in the experiment, the scientist responsible for the test did not consider this serious enough to discard the trees. Considering that the trees may have already been compromised by disease possibly unrelated to the Frostban experiment, it seems that the tests should have been repeated on healthy trees.

4. In paragraph 4 on p. 2 an adverse reaction was noted in an Elberta peach tree limb following an injection with the parental strain of P. fluorescens. After the technician reported the adverse reaction, why was that particular limb pruned off the tree? Was the limb subjected to pathological examination?

5. On p. 2, paragraph 5 the technician reports having tried to isolate RSP-36 (ice-minus derivative of P. syringae) from a canker on a Texas Mission Almond tree. Although the technician isolated organisms from the canker, the organisms were never properly characterized to determine whether or not they were P. syringae. The bacteria should have been checked biochemically (oxidase reaction, antibiotic resistance pattern, etc.).

6. Page 3 underscores the problems the researchers encountered in obtaining reproducible results with the strains of bacteria used as positive controls in the experiment. If it was difficult to obtain good results with strains known to cause disease in these plants, it may be that the conditions under which the test was conducted, were inappropriate. The proportion of the trees in the test group that allegedly developed cankers might be increased if the conditions of the experiment were altered to conform with those described in the literature referenced. If it was difficult to obtain a positive response with known pathogens under the conditions of the rooftop test (ie. vast fluctuations in temperature, uncontrolled humidity, etc.), would a negative response under these conditions with one of the experimental organisms be accurate?

7. Greenhouse experiments described on pages 3 through 5 indicate that, following the inoculation of tomato plants with P. fluorescens strains A5265R and 1776R (both ice minus derivatives), several of the leaves developed necrotic lesions. The fact that the pathological work up of the lesions identified viable, rifampicin resistant, oxidase positive, fluorescent bacteria (all characteristics of P. fluorescens ice-minus derivatives) strongly suggests that these organisms were involved in the disease condition. Koch's postulates hold that these organisms should be inoculated onto a healthy leaf to see if the disease is replicated. Table 1G of the July 1985 AGS submission to the agency reports that P. syringae RGP36 and P. floresceas GJP17B were not pathogenic. The technician does not report having used these strains referred to in Table 1G in the tomato plant study.

8. The EPA Interim Policy requires disposal or sanitation of plants, animals, soils, etc., which were exposed during or after a test of genetically-engineered organisms. What happened to the limbs that were pruned from the experimental trees? Were the trees evaluated microbiologically to determine that no test bacteria remained on the tree in the soil after the experiment?

9. How was the water from the greenhouse experiments disposed of?

10. Was protective gear worn when leaf swabs were conducted in the greenhouse?

11. Where did the technicians load the syringes used to inject the trees with the inoculate? From what sort of container were the syringes loaded with the inoculate?

12. What type of insect and animal control was used around the trees in the rooftop experiment?

13. What size needle was used?

14. What inoculum size was used? Was the inoculum size changed during the rooftop experiments? If so, why?

15. Does AGS consider a tree leaking sap at the inoculation site for a prolonged period of time a sign of possible pathogenicity? Was any sap ever evaluated to insure that it did not contain the test organism?

16. Were the trees used in the rooftop experiment ever used in earlier experiments? If so, please describe the experimental history.

17. Were any experiments conducted on Montmorency cherry trees? If so, why isn't the data reported in the EUP application?

18. Did AGS seal the injection sites on the experimental trees? If so, how did AGS seal the site?

19. What reactions were observed from the greenhouse test of soybeans using the ice-minus derivative? Where is the data reported?

20. Who wrote the official report of the results of the inoculations on the experimental trees done in March and April 1985?

21. Did all technicians record their observation notes in bound and numbered page notebooks on a daily basis? How many technicians made notes on sheets of paper on a daily basis and compiled them later in a formal lab book?

22. Who was responsible for training the technicians in conducting and evaluating the pathogenicity experiments? How many hours of formal instruction were given to the technicians? How was the technicians' competency evaluated before they were permitted to work without immediate supervision?

23. Who was responsible for explaining the NIH guidelines for the handling of genetically-engineered organisms to the technical support staff? Who was responsible for explaining the EPA interim policy guidelines under FIFRA to the senior scientists and support staff?

I appreciate EPA's immediate attention to this information and these questions. The Subcommittee staff will continue to cooperate with your investigation in any way possible.

Sincerely,

Harold L. Volkmer
Chairman
Subcommittee on Investigations
and Oversight

HLV:ssh

CONFIDENTIAL

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 24 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Honorable Harold L. Volkmer, Chairman
Subcommittee on Investigations
and Oversight
Committee on Science and Technology
House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

This is in response to your March 7, 1986 letter to Administrator Lee M. Thomas regarding the Environmental Protection Agency's (EPA's) investigation of two experimental use permits (EUPs) granted to Advanced Genetic Sciences, Inc. (AGS) of Oakland, California, to field test two genetically altered strains of bacteria which are intended to prevent the formation of ice on plants at certain temperatures. Because the investigation has been conducted by my office, I have been asked to respond to your letter.

On February 26, 1986 the Washington Post reported that AGS had acknowledged testing genetically-engineered microbial pesticides in the open air without experimental use permits from the Enviromental Protection Agency. The EPA Office of Pesticides and Toxic Substances, Office of Compliance Monitoring (OCM) immediately directed EPA Region IX inspectors to initiate an investigation of AGS. EPA's Region IX conducted an inspection at AGS on February 28 - March 6, 1986 to determine and document the facts related to the outdoor testing, greenhouse testing, and proposed field testing of the two strains of bacteria genetically altered to have non-ice nucleating characteristics. In addition, a Facilities Inspection and Data Audit was conducted by an EPA Headquarters inspection team on March 4-6, 1986. All studies with the genetically-engineered organisms, whether or not submitted to the Agency with the EUP applications, and all studies directly related to the EUP test substances, which were conducted since the applications were submitted, were included in the audit.

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On March 4, 1986, the Subcommittee on Investigations and Oversight held a hearing to investigate the allegations that appeared in the Washington Post. In preparation for the hearing, the Subcommittee Staff was provided with a document which raised questions regarding plant pathogenicity testing conducted by AGS on the genetically altered bacteria. Excerpts from this document were distributed at the hearing. These excerpts were forwarded to the audit team so that allegations raised therein could be addressed during the inspection/audit.

In your letter of March 7, 1986 to the Administrator of EPA, you noted that the Subcommittee would provide to the Agency a copy (with personal references deleted) of a confidential document if the Agency agreed, in writing, to keep the document confidential and in a secure location. The document was released by the Subcommittee to the Agency on March 12, 1986 upon receipt of written assurances from the Agency that the document would be secured in a manner consistent with existing EPA investigative security procedures.

In your letter of March 7th, you also expressed specific concerns regarding the allegations contained in the confidential document. The twenty-three points which you felt warranted examination have been addressed by the Facilities Inspection and Data Audit team. Their responses to these questions are enclosed. Please note that these responses are considered "enforcement sensitive" since they are the result of an official investigation and are the basis of an enforcement action which is open.

Based on a review of the inspection findings, the Agency has taken regulatory action to place testing under the EUPs in suspension and has issued an administrative civil complaint.

We appreciate your interest in and concern about this matter. The assistance of you and your staff has been helpful in identifying issues for this investigation. If you have any further questions regarding this investigation please feel free to contact me.

Sincerely yours,

John A. Moore
Assistant Administrator
for Pesticides and
Toxic Substances

Enclosure

ENFORCEMENT SENSITIVE

Responses of the Facilities Inspection and Data Audit Team to Concerns of the Subcommittee on Investigations and Oversight Regarding the Investigation of Advanced Genetic Sciences, Inc.

1. Were the pathogenicity tests referred to on p. 2 paragraph 3 (of the document) supposed to be conducted on dormant trees or were they to have been done on trees which had leaves?

The optimal time to conduct pathogenicity tests using Pseudomonas syringae on deciduous fruit and nut trees would be in late winter or early spring when the trees are dormant. Laboratory notes for the tree injections indicate that inoculations occurred on February 25, March 2, April 24, and, possibly, May 1, 1985. Inoculations made on February 25 and March 2 in Oakland, California would be considered near the end of the optimal time for inoculation. By April 24th, trees in that area would normally have leaves and be in an actively growing phase. In such trees, canker development is restricted. No clear explanation was given as to why there was an approximately seven week delay in completing the tree injections. The results of the injections done in April (and certainly any in May) were of questionable value for determining pathogenicity because conditions for disease development were not optimal.

2. Was the canker reported on p. 2, paragaph 3, cultured to determine whether or not the ice-minus bacteria caused the canker?

According to laboratory notes made by the technician responsible for the tree pathogenicity tests, isolations were made from cankers on a Texas Mission almond on May 23, 1985 and June 27, 1985. No bacteria were isolated that produced the typical fluorescence characteristic of RGP-36 (ice minus derivative of P. syringae) when grown on King's B media. There are no indications that further attempts to identify the cultures were made.

3. When wounds were discovered on the trees prior to their use in the experiment, the scientist responsible for the test did not consider this serious enough to discard the trees. Considering that the trees may have already been compromised by disease possibly unrelated to the Frostban experiment, it seems that the tests should have been repeated on healthy trees.

AGS personnel supervising the tree pathogenicity tests instructed the technician not to use branches of trees which showed symptoms of disease. However, other branches on a tree, which were apparently healthy, were used for the pathogenicity tests. In the opinion of some plant pathologists, completely healthy trees should be used to be certain of reliable test results.

Recent correspondence from AGS indicates that they intend to repeat certain tree pathogenicity studies.

4. In paragraph 4 on p. 2 an adverse reaction was noted in an Elberta peach tree limb following an injection with the parental strain of P. fluorescens. After the technician reported the adverse reaction, why was that particular limb pruned off the tree? Was the limb subjected to pathological examination?

According to Drs. Suslow and Lindemann, senior scientists responsible for the project, and to Mr. Tom Lemieux, the greenhouse manager, the branch was pruned by accident. No examination of the reaction was attempted. According to AGS personnel, all pruned material was routinely placed in a biohazard bag and autoclaved before disposal.

5. On p. 2, paragraph 5 the technician reports having tried to isolate RGP-36 (ice-minus derivative of P. syringae) from a canker on a Texas Mission Almond tree. Although the technician isolated organisms from the canker, the organisms were never properly characterized to determine whether or not they were P. syringae. The bacteria should have been checked biochemically (oxidase reaction, antibiotic resistance pattern, etc.).

The technician's notes indicate that colonies of microorganisms were grown on isolation plates. Five colonies were subcultured to nutrient agar slants, incubated to allow growth and subsequently stored in a cold room at AGS. Upon inquiry, Dr. Lindemann showed a member of the EPA audit team to the cold room (AGS room #364) and located the technician's cultures. Five test tube slants were found labeled 5003, 5004, 5005, 5006, and 5007 corresponding to the designation indicated in the laboratory notes. The tubes were covered with plastic closures (caps), wrapped with parafilm strips, and the test tube holder enclosed in a plastic bag sealed with a twist tie. The bag was labeled "DB; June 1985". On cursory observation, it appeared that at least three different organisms had been isolated. The streaks of organisms in slants 5003 and 5004 had a translucent, moist, creamy appearance. Those on slants 5005 and 5006 had a white, opaque appearance. The streak on slant 5007 was a bright yellow with rough, dry edges. There was no representation in the technician's notes of the variety or number of colonies that appeared on the isolation plate. The notes said "small, white colonies isolated". There was no indication that the slants had been subcultured, i.e. the streak patterns were undisturbed. No attempt was made on the part of AGS to identify or characterize these particular isolates since they did not resemble the organism in question.

6. Page 3 underscores the problems the researchers encountered in obtaining reproducible results with the strains of bacteria used as positive controls in the experiment. If it was difficult to obtain good results with strains known to cause disease in these plants, it may be that the conditions under which the test was conducted were inappropriate. The proportion of the trees in the test group that allegedly developed cankers might be increased if the conditions of the experiment were altered to conform with those described in the literature referenced. If it was difficult to obtain a positive response with known pathogens under the conditions of the rooftop test (i.e., vast fluctuations in temperature, uncontrolled humidity, etc.), would a negative response under these conditions with one of the experimental organisms be accurate?

Positive controls generally gave positive results on the trees injected on February 25 and March 2, 1985. Positive results with positive control organisms were less frequent following the April 24th injections. The lack of positive results from positive controls for the April 24th injections reduces the confidence in the results of all treatments injected on that date.

7. Greenhouse experiments described on pages 3 through 5 indicate that, following the innoculation of tomato plants with P. fluorescens strains A5265R and 1776R (both ice minus derivatives), several of the leaves developed necrotic lesions. The fact that the pathological work up of the lesions identified viable, rifampicin resistant, oxidase positive, fluorescent bacteria (all characteristics of P. fluorescens ice-minus derivatives) strongly suggests that these organisms were involved in the disease condition. Koch's postulates hold that these organisms should be inoculated onto a healthy leaf to see if the disease is replicated. Table 1G of the July 1985 AGS submission to the agency reports that P. syringae RGP-36 and P. fluorescens GJP17B were not pathogenic. The technician does not report having used these strains referred to in Table 1G in the tomato plant study.

The greenhouse experiments described on pages 3 through 5 were conducted as part of a program to evaluate SNOMAX, an AGS product derived from non-genetically altered bacteria. The organisms involved in these experiments are not the same strains as the organisms involved in the Frostban EUP applications.

Koch's postulates were not verified because the senior researchers felt that they and their staff had sufficient experience to identify the disease by observing the symptoms. This is a common procedure in situations where a known pathogen is used on a susceptible species and the symptomolgy is well-documented and familiar to the investigator.

8. The EPA Interim Policy requires disposal or sanitation of plants, animals, soils, etc., which were exposed during or after a test of genetically-engineered organisms. What happened to the limbs that were pruned from the experimental trees? Were the trees evaluated microbiologically to determine that no test bacteria remained on the tree or in the soil after the experiment?

The tree limbs used in the roof top experiment were pruned by the greenhouse staff. Mr. Tom Lemieux, the greenhouse manager, told the audit team that these limbs were removed proximal to the identification tape (below the injection sites) and cut into pieces approximately 8 to 10 inches in length. According to Mr. Lemieux, these were collected in an autoclavable bag marked "biohazard", sterilized in the autoclave using standard procedures and discarded with the trash. Although the EPA Interim Policy requires that information concerning the method of disposal be included in the notification, it does not specify the method of disposal.

There was no attempt on the part of AGS to culture the remaining parts of the trees or the soil for the test bacteria.

9. How was the water from the greenhouse experiments disposed of?

Drainage water in four of the greenhouses collected in puddles under the work benches. According to AGS personnel, when experiments involving genetically-engineered organisms were in progress, this water was collected in cans via a portable, electric sump pump, treated with sodium hypochlorite and disposed of in building drains. According to AGS personnel, for such experiments carried out in the two greenhouses which have permanently installed drains, the drainage water was collected in saucers under the plant pots. This water was pooled and treated as above.

10. Was protective gear worn when leaf swabs were conducted in the greenhouse?

According to AGS officials, protective clothing was recommended when experiments involving genetically-engineered organisms were in progress and the personnel were working directly with plants. The protective clothing available included cloth lab coats and disposable gloves, shoe covers, masks, and caps. It is not known if these procedures were strictly adhered to by the staff at all times.

11. Where did the technicians load the syringes used to inject the trees with the inoculate? From what sort of container were the syringes loaded with the inoculate?

The syringes used in the tree experiments were loaded on the roof top. The prepared inocula were transported from the laboratory to the roof in stoppered glass laboratory flasks (25 to 250 mL).

12. What type of insect and animal control was used around the trees in the rooftop experiment?

No special precautions were used to control insects or animals around the trees used in the roof top experiment. Pesticide spraying was done on a routine basis or when the scientific staff felt that it was necessary. When the tree injection experiment was in progress, however, the trees were not sprayed.

13. What size needle was used?

According to AGS officials, the trees were injected using a 3 cc disposable syringe and a 26 gauge needle. Mr. Brosten, the former AGS technician who performed the injection experiments, said in an interview that he used a 25 gauge needle.

14. What inoculum size was used? Was the inoculum size changed during the experiments? If so, why?

According to laboratory notes reviewed by the EPA audit team at the AGS facility, 10^7 colony forming units (CFU)/mL or 10^5 CFU/mL were used in the tree injection experiment. The 10^7 CFU/mL size was used on February 25 and March 2 and the 10^5 CFU/mL size was used on the April 24 injections. Either 10^7 or 10^5 CFU/mL sizes should be effective dosages if other conditions were appropriate for disease development. Dr. Lindemann, the technician's supervisor, stated that she was unaware of the fact that the inoculum dosage had been reduced and that she had not told him to lower the dosage for the April injections. The technician's laboratory notes are unclear as to how the dilutions of the bacterial suspensions were made.

15. Does AGS consider a tree leaking sap at the inoculation site for a prolonged period of time a sign of possible pathogenicity? Was any sap ever evaluated to insure that it did not contain the test organism?

AGS scientists indicated that they did not consider leaking sap, in and of itself, to be an indication of disease. Although typical Pseudomonas syringae cankers on deciduous fruit and nut trees are slightly sunken, dark brown in color, and may exude gum (thick, sticky substance) from the infected areas, gums may also be produced following injury such as a pruning cut, or infection such as a boring insect. A prolonged period of gumming (or "leaking sap") would be considered a sign of possible pathogenicity. The technician involved in the tree injection experiments attempted unsuccessfully to isolate the test organism from suspected cankers.

16. Were the trees used in the rooftop experiment ever used in earlier experiments? If so, please describe the experimental history.

According to AGS officials, some of the trees used in the rooftop experiment were used in earlier studies. Those studies were conducted in the greenhouse to estimate colonization potential of the ice minus derivative organisms. At the end of the experiment, and after repeated attempts to culture the test strains were negative, the trees were placed in a corner of the greenhouse for approximately two months before being used again. These included some of the almond, cherry, and pear trees. Trees were not individually tracked, and it cannot be determined which of them were or were not re-used in the rooftop experiment. Peach, plum, apricot, and apple trees were newly purchased for the rooftop experiment.

17. Were any experiments conducted on Montmorency cherry trees? If so, why isn't the data reported in the EUP application?

The EPA audit team confirmed that the rooftop experiment included Montmorency cherry trees. It also included Bing and Black Tartarian cherry trees. It is not clear why the results from the Montmorency cherry tree injections are not included in the EUP applications because the results of the Bing and Black Tartarian cherry trees are cited.

18. Did AGS seal the injection sites on the experimental trees? If so, how did AGS seal the site?

The injection sites on the experimental trees were not sealed. AGS personnel concluded from discussions with other scientists (outside AGS) that wrapping the inoculation sites might encourage molds to grow that would mask symptoms which might develop after injection with bacterial suspensions or buffer controls.

19. What reactions were observed from the greenhouse test of soybeans using the ice-minus derivative? Where is the data reported?

Ice-minus derivatives RGP-36 and GJP-17B were tested on Glycine max (L.) Merrill cv. 'Cumberland'. The data are reported in the EUP application (Table 1g). No adverse effects were noted. A positive control group, challenged with a known pathogenic strain exhibited adverse effects.

Additional pathogenicity studies were conducted after the EUP application was submitted. Soybeans were included, along with a wide variety of plants. Data were recorded in AGS notebooks and has not been reported elsewhere.

20. Who wrote the official report of the results of the inoculations on the experimental trees done in March and April 1985?

Dr. Julianne Lindemann wrote the section of the EUP application which discussed the results of the inoculations on trees. In preparing this she used the summary notes of the technician who performed the experiment, her own observations recorded in her notebook and mental notes.

21. Did all technicians record their observation notes in bound and numbered page notebooks on a daily basis? How many technicians made notes on sheets of paper on a daily basis and compiled them later in a formal lab book?

Although some of the technicians at AGS may routinely record original observations into bound and numbered page notebooks on a daily basis, those interviewed and/or observed at AGS typically transferred their notes from loose pieces of paper to a bound notebook. There was no apparent company policy regarding the maintenance of laboratory notebooks or entering data into the notebooks.

22. Who was responsible for training the technicians in conducting and evaluating the pathogenicity experiments? How many hours of formal instruction were given to the technicians? How was the technicians' competency evaluated before they were permitted to work without immediate supervision?

Generally, Dr. Lindemann gave instructions, both written and oral, to the technicians who conducted pathogenicity experiments. Technicians had training in plant pathology or microbiology and had either BS or MS degrees. Technicians were provided with access to written protocols, published laboratory manuals, and original scientific literature. Technicians did not receive formal training at AGS, but this would not be expected at such a research facility when technicians had formal university training. Technicians were shown how to conduct experiments if they had never done them before and their work was checked for technical accuracy.

23. Who was responsible for explaining the NIH guidelines for the handling of genetically-engineered organism to the technical support staff? Who was responsible for explaining the EPA interim policy guidelines under FIFRA to the senior scientists and support staff?

NIH guidelines and EPA policy documents were distributed to the scientific staff. The staff was left to make their own interpretations and conclusions. In the case of the roof top experiment, Drs. T. Suslow and J. Lindemann were responsible for deciding on the appropriateness of the study design and the procedures for handling the test organisms.

An Institutional Biosafety Committee is now in place which will review such decisions. It has no direct link to AGS management.